ASR
ARCHIVES of SURGICAL RESEARCH

Archives of Surgical Research

A Peer Reviewed Journal of Surgical Research & Education

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Archives of Surgical Research (ASR) is dedicated to the local, national, and global advancement of surgical research, education and clinical practice. It aims to promote continued development in surgery through the dissemination of knowledge, ideas and good practice across surgical specialties. ASR provides readers with critically peer-reviewed, carefully selected and edited, and up-to-date publications about advancements in all surgery specialties.

As a journal covering all surgical specialties, ASR aims to facilitate the transfer of important ideas and thought systems between and across specialties. Hence, ASR will help prevent the trend of increasing sub-specialization which leads to 'tunnel-vision' and the unfortunate concealment of important surgical advances within specific specialties.

Published by
Pakistan Endocrine & Thyroid Surgeons Association (PETSA)
537-S, Imperial Garden Homes, Paragon City, Lahore, Pakistan

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Editor in Chief: Prof Khwaja M Azim FRCS

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About Archives of Surgical Research

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The journal aims to uphold the highest standards at the cutting-edge of research, provide a focus for evidence-based medicine through the publication of review articles and special issues, and give the findings context through the publication of editorials, commentaries and letters from the surgical community. We ensure enforcement of reporting guidelines and mandate the registration of all research involving human participants in a publicly accessible research registry.

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Editor in Chief

KMA

Editorial Team

PREFACE

Shalamar Medical & Dental College has exceptionally excelled in the field of science, education and research over the last decade and has produced quality graduates who are currently serving around the world. Quality of education and research in surgery has been instrumental in this regard under the leadership of Prof Khawaja Muhammad Azim to achieve our core objective of producing quality education. Inception of Pakistan Endocrine & Thyroid Surgeons Association (PETSA) has aligned well to my vision, institutional requirements and overall rapport of the institution.

I witnessed and supported the birth of Pakistan Endocrine & Thyroid Surgeons Association here at Shalamar Medical College three years back and during this period it has evolved into a mature tree and is bearing fruits to surgical education and training here at our institution. Legacy of its founding visionary, Late Prof Syed Zafar Haider has continued. PETSA has been conducting Annual Thyroid & Parathyroid Master Class since its inception with great reception. Currently, we are the largest endocrine surgery center in Pakistan with highest volume turnover.

Now the introduction of "Archives of Surgical Research" is another feather into our institutions' cap. This journal would not only satisfy the needs of the society but would also serve to promote culture of science, education and research within our institution. This culture advocacy remains instrumental in promoting the quality of learning process of the medical graduates within our institute and is aligned with my vision about this medical college.
In the end, I am happy to write about "Archives of Surgical Research" and its inaugural issue and wish the editorial team best of luck for their endeavors for years to come.

Prof Zahid Bashir

Principal

Shalamar Medical & Dental College, Lahore

MESSAGE FROM THE PRESIDENT

Pakistan Endocrine & Thyroid Surgeons Association (PETSA)

Prof Zafar Haider was the teachers of the teachers and a great surgeon. He was the one who made thyroid and endocrine surgery safe in Pakistan and we carry the light now with aim to improve the endocrine surgery in light of modernization in the field of the surgery.

Archives of Surgical Research aims at improving the standard of surgical research and education. It would function as official Journal of Pakistan Endocrine & Thyroid Surgeons Association (PETSA).

The journal would cover endocrine, breast and surgical oncology primarily. It would also focus on the surgical education for medical students and residents to enhance the learning process through addition of technology, blended learning and modern concepts in medical education.

Prof. Khwaja M Azim FRCS
President PETSA

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Stomach or Colon for Esophageal Replacement? What Prof Haider thought!

Talat Waseem

IMPORTANCE Prof Syed Zafar Haider has been the most influential surgical trainer in the history of Pakistani surgical community. He has influenced number of current and past surgical giants with his own style, quality and discipline and fortunately me as well. He pioneered trans-hiatal esophagectomy in Pakistan. In this brief writing I would share a letter written by Mark Orringer to Prof Haider weighing stomach vs colon for esophageal replacement. This letter here attached was written by Dr Orringer from University of Michigan to Shah sb. This is a glimpse of historic correspondence between two surgical giants, in which they weigh colon vs. stomach for esophageal replacement.

KEYWORDS Esophageal replacement, colonic interposition,

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ZH Memorial Feature

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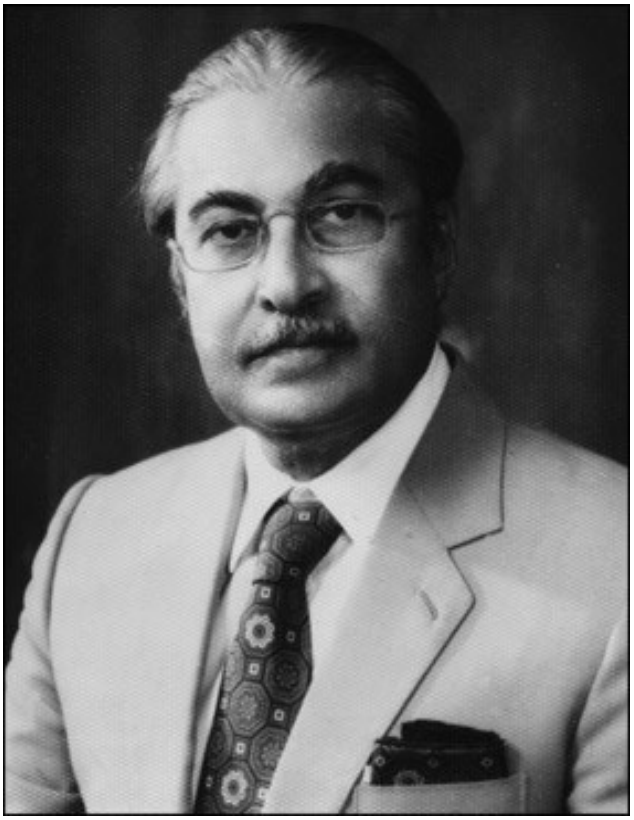
https://doi.org/10.48111/2020.04.01

Prof Syed Zafar Haider has been the most influential surgical trainer in the history of Pakistani surgical community. He has influenced a great number of current and past surgical giants with his own style, quality and discipline and fortunately me as well. I have not seen another self-less educator, like he was. Most of my surgical training is through Prof Khwaja M Azim, a great surgical excellence himself, who learned all from Great Prof Haider. Through him, I had brief but very meaningful interactions with Shah sb in terms of surgical career direction.

After retirement he served at Shalamar Hospital for almost a decade and later voluntarily taught surgical graduates of Shalamar Medical and Dental College. In the last few years of his life, considering his passion to teach, we convinced him to teach the Shalamar Graduates. My job was to facilitate him in this process. His style of teaching the students was superb. He was true reflection of Koen's Model of learning in which every lesson had clinical preamble and perspective to enhance cognitive retention of students. Apart from using conventional means of training he believed in technology and adaptation. For every lesson he had self-made lectures, slides and handouts showing his devotion to the process of teaching and training.

One day, he brought me a letter that he received from Mark Baker Orringer, a pioneer in Trans-hiatal Esophgectomy. To my knowledge, he started doing esophagectomy in Pakistan in the same period in Nishter Medical College Multan, when it was popularized by Dr Orringer in USA. For an hour we talked about esophageal replacement. He always preferred stomach over colon for number of reasons and he shared the approaches he used and why. This letter here attached was written by Dr Orringer from University of Michigan to Shah sb. This is a glimpse of historic correspondence between two surgical giants, in which they weigh colon vs. stomach for esophageal replacement. The inference of this letter still stands true even after 35 years of advancement in esophageal surgery.



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March 20, 1985

Professor S. Zafar Haider, FRCS
(England)
Professor of Surgery
K.E. Medical College
Mayo Hospital
1 5-A Hali Rd.
Gulberg II, Lahore
PAKISTAN

Dear Professor Haider:

Thank you for your letter of March 5, 1985, regarding your experience with transhiatal esophagectomy without thoracotomy. Having now performed this operation in more than 250 patients, approximately 150 with carcinoma, and 100 with various benign diseases of the esophagus, including caustic strictures, I am more than convinced of the efficacy of this operation in achieving esophageal resection and replacement with the least morbidity possible. As I have indicated in my publications regarding this operation for carcinoma, I believe that our 95% resectability rate through the hiatus for our patients with carcinoma is indicative of the fact that we do not see patients with very far advanced tumors. I remain extremely pleased with the use of stomach as an esophageal replacement for benign disease requiring esophagectomy, and I believe that the long-term functional results with stomach are better than those obtained with colon interposition.

Thank you again for your very kind letter.

Sincerely yours,

Mark B. Orringer

Mark B. Orringer, M. D.
Professor of Surgery
Director, Thoracic Surgery Esophageal Clinic

MBO/150/bm

Archives of Surgical Research | Editorial

The Rising Need for Endocrine Surgery Fellowship in Pakistan

Khwaja M Azim, Hira Ashraf

IMPORTANCE Globally the incidence of endocrine diseases has increased significantly. In addition, incidence of thyroid cancer is rising more than any other form of cancer. Owing to increase in endocrinopathies the demand of advanced endocrine surgical training has increased. In face of the growing demand of endocrine surgeons worldwide, Pakistan Endocrine & Thyroid Surgeons Association was formed as a representative body of Pakistani surgeons with special interest in endocrine surgery. Pakistan is ranked third in anticipated population growth spurt between 2015-2050. Surgical burden is anticipated to increase with growing population due to increase in incidence of endocrine diseases and thyroid cancer. There is a dire need of advanced training in endocrine surgery in Pakistan.

KEY WORDS Endocrine Surgery Fellowship, Endocrine Surgery, Thyroid Surgery, Adrenal Surgery, Endocrine Surgery Training

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Editorial

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Endocrine surgery is a surgical subspeciality focusing on the study of surgical management of various diseases of thyroid gland, parathyroid glands, adrenal glands and neuroendocrine tumors of gastrointestinal tract and pancreas[1–4]. For a long time, endocrine glands were considered to form an integrated system. Endocrine surgery has been practiced for hundreds of years. However, it was recognized in the beginning of 20th century. By the middle of twentieth century surgeries of all known endocrine glands had been performed more so often of thyroid and parathyroid glands. However, endocrine surgeries were performed more commonly and with greater safety after the advent of cortisone and endocrine surgeries began to be viewed as a whole. As study in endocrinology advanced syndromes of hypersecretion were identified. Surgeons became increasingly involved in curing these metabolic syndromes via surgical interventions. Henceforth, in later half of twentieth century endocrine surgery started emerging as a new discipline in general surgery.

Globally the incidence of endocrine diseases has increased significantly. In addition, incidence of thyroid cancer is rising more than any other form of cancer. Owing to increase in endocrinopathies the demand of advanced endocrine surgical training has increased. Surgical endocrine disorders are managed by general surgeons, upper and lower gastrointestinal surgeons, otolaryngologists, head and neck surgeons, surgical oncologists and urologists. Only a handful of surgeons have dedicated their service in this discipline. Worldwide only 11 countries have professional body of endocrine surgery. Increase in endocrine surgical burden has led to increase in demand of dedicated training in endocrine surgery.

There are only a few endocrine centers worldwide. In face of the growing demand of endocrine surgeons worldwide, Pakistan Endocrine & Thyroid Surgeons Association was formed as a representative body of Pakistani surgeons with special interest in endocrine surgery[3]. Pakistan is ranked third in anticipated population growth spurt between 2015-2050. Surgical burden is anticipated to increase with growing population due to increase in incidence of endocrine diseases and thyroid cancer. There is a dire need of advanced training in endocrine surgery in Pakistan. In Pakistan due to relative scarcity of endocrine surgeons the bulk of endocrine surgeries are performed by surgeons without specific interest or advanced training in the field. Better outcomes can be achieved if surgeons with advanced training in the field manage these patients.

Most surgical endocrine diseases are managed by general surgeons who have developed special interest in the field and have modeled research endeavors accordingly. However, the recent generation requires endocrine surgeons with formal fellowship training in endocrine surgery. Increase in endocrine diseases has not only led to increase in demand of dedicated endocrine surgeons but also an increased interest in advanced endocrine surgical training. A rapid growth of this specialty is required both in quality and in quantity.

Endocrine surgery fellowship program can offer to fill a significant gap in the existing health care system of

Pakistan. Trainees can have a dedicated expertise in this field. During the fellowship trainees will be offered exposure to management of thyroid gland, parathyroid glands, adrenal glands and neuroendocrine tumors of pancreas and gastrointestinal tract. This field inherently requires multidisciplinary exposure to endocrinology, medical oncology, pathology, radiology and genetics. Dedicated expertise in traditional and modern surgical procedures and familiarity with ongoing research will offer to counter the scarcity by training leaders and policy makers in endocrine surgery.

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Archives of Surgical Research | Original Investigation

How to Decide for Drain Placement in Thyroidectomy: Qualitative Exploration to Formulation of a Decision Tree

Talat Waseem, Safia Zahir, Zaitoon Zafar, Muhammad Hasham Ashraf

IMPORTANCE Contrary to significant clinical evidence, many surgeons still use drains following a thyroidectomy for several reasons, including intent to prevent postoperative hemorrhage and seroma formation. Quality of hemostasis, size of gland, quality of thyroid tissue and its dissection, presence of adhesions and extent of surgery may all influence surgeon's decision to use a drain. The aim of this study is to qualitatively explore the reasons for use of drains in thyroidectomy, to evaluate given reasons in a clinical setting and finally, to develop a consensus decision tree.

METHODS We conducted a thematic analysis following a focused group discussion among panel of endocrine surgical experts (n=8) to explore the factors which influence the decision to place a drain following thyroidectomy. To validate these findings, we conducted a prospective randomized clinical trial on patients undergoing thyroid surgery. Patients were randomly assigned to a drain group (n = 112) or a no-drain group (n = 100). Postoperatively, we evaluated visual analogue scale pain scores, postoperative analgesic requirements, self-reported scar satisfaction at 6 weeks and complications associated with surgery including hemorrhage and seroma formation. E-Delphi technique was used to develop a consensus on the proposed decision tree.

RESULTS Thematic analysis of the focused group discussion of panel of endocrine surgeons revealed various factors involved in the decision of placing or not placing a drain. Reasons included quality of dissection, size of gland, extent of dissection, thyrotoxicosis associated tissue friability and thyroiditis, or cancer associated fibrosis. Technique of dissection and experience were considered to be the most important determinant of postoperative hemorrhage. Purpose of drain placement was not to prevent hemorrhage, but to provide a sense of comfort to the operating surgeon. Clinical trials revealed no significant impact of drains in prevention of hemorrhage, however, drain placement was significantly associated with lower rates of postoperative seroma formation. Subgroup analysis showed a higher association of seroma formation to extent of surgery, size of gland and thyrotoxicosis. A decision tree to aid decision making for drain placement during thyroidectomy is being proposed here.

CONCLUSIONS The decision to place the drain should be selective. Size of the gland, extent of dis-section, thyrotoxicosis and quality of hemostasis are important determinants for the decision of drain placement justifying the selective use of drains. The frequency of life-threatening post-thyroidectomy bleeds remains low and drain placement might not be required for smaller thyroid nodules. Short term drain placement for 12-24 hours reduces seroma formation and, thus, need for needle aspiration in patients undergoing thyroidectomy.

KEY WORDS Thyroidectomy, Drain Placement, hemorrhage, seroma formation

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Original Investigation

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Emerging evidence challenges routine use of drains in many surgical procedures because of higher infection rates, discomfort and prolonged hospital stays [1–5]. Their clinical utility has been questioned in colonic and biliary surgery and in fact their use has reduced significantly [1,6,7]. Thyroid surgery is no exception. Following these lines many studies have discouraged the use of drains, even in the neck, with the belief that drains do not prevent hemorrhage[7–14]. The evidence is statistically convincing however the practice has lagged, in opposition to literature recommendations. Many surgeons still use drains after performing thyroid surgery and have a selective approach[15]. Early recognition of hemorrhage, fear of formation of neck hematoma or prevention of seroma formation are the three most cited reasons for placing drains in neck[16]. On the contrary, drains can augment infection, may influence the wound scar quality, can lead to more pain, and may prolong hospital stay[9,16,17].

This discrepancy between literature recommendations and prevalent practices potentiates the need for randomized trials but despite many randomized trials, many aspects of the drain placement decision still remain unexplored. To explore reasons for drain placement we here employ the qualitative approach and examine the perceptions and their scientific justification. To further corroborate our qualitative findings, we conducted a randomized controlled trial. The objective of the study is to critically probe the reasons for placing a drain following neck surgery and with the eventual aim to minimize the gap between theory and practice.

METHODS

Ethical approval for the study was obtained through institutional review board. Mixed method study design was chosen, with stage 1 comprising a qualitative approach and stage 2 comprising quantitative data collection in clinical setting, where findings of the first stage were validated in quantitative fashion. In stage 3, based on the data, a proposed decision tree was circulated among the panel of experts to build consensus through e-Delphi technique as described previously 18. Qualitative research has the power to explore details of the experiences and perceptions and may work where quantitative research has limitations. Focus group discussion (FGD) which is a very comprehensive qualitative data collection technique, was used here, as described previously, in this study to explore perceptions and experiences of expert endocrine surgeons about drain placement[19]. To identify prevalent themes in drain placement, challenges, advantages and disadvantages, extensive literature review was done and a discussion guide was made for the FGD session. Open ended and closed ended questions were formulated for discussion. Descriptive exploratory qualitative study using a conventional content analysis method was performed. Purposive sampling of the eight (n=8) experts was done to include the surgeons who are well trained and have extensive experience in endocrine surgery and have performed at least 200 thyroidectomies. Our sample size conforms to literature recommendations [19]. Focus group discussion was conducted in standard fashion with the point of saturation as described previously by Strauss [20]. The session was audio-recorded. A qualitative content analysis was performed as described previously by Graneheim and Lundman [21]. Analytical process started by using verbatim transcription and identifying the participants' views. Themes, subthemes and categories were identified and negotiated between the team members to generate inter-rater reliability. As of any qualitative research the quality of study was ensured on the criteria of credibility, transferability, dependability, and confirmability.

In stage 2 of the study, a prospective randomized clinical trial was conducted following principles of the CONSORT flow diagram. The trial involved patients undergoing elective thyroidectomy with or without drain. The patients having small and moderate sized glands were included in the study and the patients with large or huge glands were excluded from the study. General demographics of the participants, disease, gland size, clinical status and clinical diagnosis parameters were recorded as per norms. The randomization was through the lottery method. The primary study end point was seroma formation and hemorrhage necessitating re-exploration. Secondary end points included postoperative pain (assessed by visual analgia scoring and analgesia requirements according to the WHO analgesia ladder system) at 24 hours, drain output and length of hospital stay. Patients requiring extensive surgery like sternotomy, thyroidectomy for huge glands, neck dissection and with history of any bleeding disorder were excluded. Both surgeons and the patients were blinded to randomization. Two surgeons employed the same operative technique to provide uniformity. Meticulous hemostasis was ensured prior to closure. Suction drain was used prior to closure for the drain group. Preoperative analgesia was standardized. Type and length of surgery recorded. Operative time, blood loss, postoperative drain volume, analgesia requirements, histological diagnosis and recurrence over a period of at least 6 months recorded. Postoperative pain was assessed through visual analogue scoring ranging from 0-10. Postoperative complications like acute life-threatening post-thyroidectomy bleed, neck hematoma and symptoms of hypocalcemia, were recorded both throughout the hospital stay and at the first scheduled clinic appointment after surgery (6 weeks postoperatively). A wound infection was diagnosed if purulent discharge exuded from the wound or a painful, spreading erythema indicative of cellulitis existed. At six weeks, patient satisfaction with scarring was assessed by subjective patient ranking on a scale from 0 to 10.

In Stage 3, e-Delphi technique was used as described previously to build expert consensus on proposed decision tree for drain placement in 2 rounds.

Statistical Analysis of Results

The data was analyzed using SPSS version 21 (SPSS, Inc, Chicago, IL, USA). Data normality was tested using the Kolmogorov-Smirnov test. Fisher's exact test or Pearson Chi2 values were used to determine significant difference between the groups. For linear data with means, Mann-Whitney U test was used as appropriate. A value of $P < 0.05$ was considered to be statistically significant. Inter-rater agreement and concordance were calculated based in Fleiss's kappa values with cut off of 0.8.

RESULTS

The study consists of three stages: first stage encompasses qualitative portion and the second stage is a quantitative study in form of a randomized controlled trial. Figure 1 shows the flow of the study and its two stages. In third stage we propose a consensus decision tree based on data. Extensive preliminary literature review was done, based on which themes and subthemes were identified to understand

the reasons of drain placement. A discussion guide was formulated to standardize the discussion. Eight experts in endocrine surgery participated in Focus Group Discussion (FGD). The themes explored have been summarized in the Table 1.

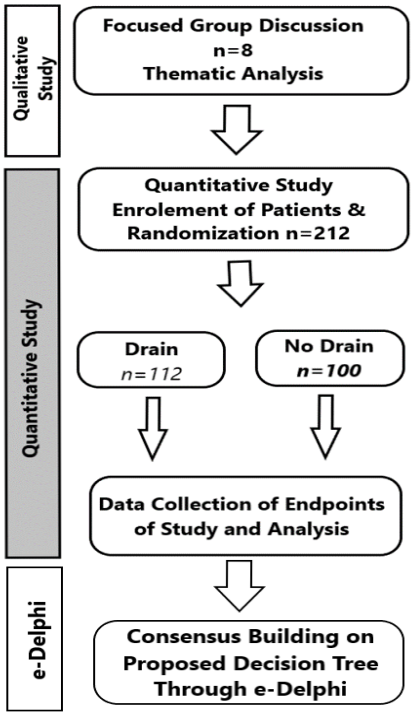

Figure 1: The Flowchart shows the overview of the study steps and its qualitative and quantitative components.

Theme	Subtheme	Representative Statements
actors influencing Placement of Drain	Hemorrhage & Apprehension of Bleed	*"Well it is all about fear of bleed"* *"Conventionally I have believed in drains in neck surgery-It is reassuring and it does not hurt me or the patient"*
	Size & Extent of Dissection	*"For smaller glands I may be able to skip the drain but for the larger glands, usually it becomes harder for me to avoid a drain"* *"I think size of the gland and toxicity often force me to put in drain"*
	Friability & Fibrosis	*"Toxic glands are quite friable and the surrounding tissues are also hyper-vascular and they bleed to touch. Invariably I would have to place a drain in these cases"* *"Preoperative Lugol's Iodine treatment partially reduces vascularity of the gland and reduces friability of the gland however I always put a drain in such cases"*
	Adhesions	*"Adhesions are also important, whether they are due to malignant thyroidal lesion or thyroiditis related fibrosis, they all lead me to put in a drain"*
	Seroma Formation	*"For smaller glands, there are lower chances of seroma development-these are probably the cases where we can avoid the drain"* *"Seroma formation may also be linked to body's response to dissection and the sutures used for tying vessels".* *"When there is extensive area of dissection for example in total thyroidectomy for large glands, there is higher chance of bleed and seroma formation if we don't put in a drain"*
Prevention of Hemorrhage	Technique & Quality of Hemostasis	*"It all depends on technique, careful dissection and quality of hemostasis"* *"I had few bleeds in my career and they all were related to technical failure and that was mostly slippage of ligature of a vein; I always tie twice!"* *"Whenever I re-explored for bleed mostly it was due to missing on either small lateral or inferior thyroid vein and drain did not prevent neck hematoma formation"*
Advantages of Drain Placement	Reassurance	*"It is quite reassuring for me"* *"I am not sure if it would prevent hemorrhage but it keeps me calm and reassured"*
	Possible Prevention of Hemorrhage	*"The drains frequently have from few mls to up to few hundred ml of blood which shows that it is probably beneficial somehow to have it probably we would need a huge to trial to prove it statistically, however"*
	Reduction of Seroma Formation	*"It does reduce the incidence of postoperative seroma formation"*
Disadvantages of Drain Placement	Discomfort & Pain	*"Well it does add to patient discomfort"* *"Patient have more pain when a drain is there and the patients without drain are more comfortable"*
	Hospital Stay	*"However, I don't think it should add significantly to patient hospital stay"*
Avoiding Drain Placement	Smaller Glands-Minimal Dissection	*"For smaller non-toxic lobes I usually avoid drains"* *"Good hemostasis is the key for me to decide in favor of not putting the drain"*
Need or Reassurance?	Reassurance	*"it is both reassuring to put in a drain and it also prevents the postoperative seroma formation"*
	Prevention of Seroma Formation	*"I think it is ok to put in a drain for 12-24 hours or so, it is not only reassuring for me but also reduces the incidence of postoperative seroma formation"*

Table 1: Thematic analysis of qualitative interviews exploring the need for drain placement following thyroidectomy

Factors influencing the decision of drain placement were explored. Contrary to what the literature states, the fear and apprehension of neck hematoma needing evacuation still has some role to play in decision making. This varies between surgeons and few believe in the literature evidence but would still like to decide on case to case basis. One participant said: "Well this is all about fear of bleeding". This notion was expressed by another participant in following words: "conventionally I have believed in drains in neck surgery—It is reassuring and it does not hurt me or the patient". This highlights the potential role of personal biases playing in the decision of drain placement. When further scrutinized one participated in favor of placing drain claimed: "the drains frequently have from few mls. [milliliters] to up to few hundred ml of blood which shows that it is probably beneficial somehow to have it— we would

probably need a huge trial to prove it statistically, however". This does merit further investigation.

Gland size and extent of dissection play an important role in terms of apprehension about hemorrhage and the seroma formation as well as described by one participant: "For smaller glands I may be able to skip drain but for the larger glands, usually it becomes harder for me to avoid [it]" and"when there is extensive area of dissection for example in total thyroidectomy for large glands, there is higher chance of bleed and seroma formation if we don't put in a drain". For smaller glands, surgeons tended to avoid placing drains.

Third salient determinant for placement of drain that emerged was friability and the fibrosis of gland or adhesions to the surrounding structures. According to one participant, "toxic glands are quite friable and the surrounding tissues are also hyper-vascular and they bleed to touch. Invariably I would have to place a drain in these cases". When asked if there was any way to reduce the vascularity of the gland, one participant responded: "preoperative Lugol's Iodine treatment partially reduces vascularity of gland and reduces friability of gland however I always put a drain in such cases". Similarly, fibrosis and adhesions can also influence the resection bed and may lead to decision of the drain placement. In words of one expert surgeon, "adhesions are also important, whether they are due to malignant thyroidal lesion or thyroiditis related fibrosis, they all lead me to put in a drain".

The size of the gland and extent of dissection and quality of hemostasis also correlate positively to postoperative seroma formation. "For smaller glands, there are lower chances of seroma development— these are probably the cases where we can avoid the drain". One participant pointed towards the varying responses of the patient's immune system to dissection and the sutures used for tying vessels…… "seroma formation may also be linked to body's response to dissection and the sutures used for tying vessels". Area of dissection clearly was pointed as the a potentially decisive aspect. As per one surgeon: "When there is extensive area of dissection for example in total thyroidectomy for large glands, there is higher chance of bleed and seroma formation if we don't put in a drain"

Quality of hemostasis would often dictate surgeons to use or not to use the drain following thyroid surgery as explained by one endocrine surgeon this way: "It all depends on technique, careful dissection and quality of hemostasis","I had few bleeds in my career and they were all related to technical failure and that was mostly slippage of ligature of a vein; I always tie twice!" Ligature of the veins is the most frequent cause of hematoma as described by one participant: "whenever I re-explored for bleed mostly, it was due to missing on either small lateral or inferior thyroid vein and drain did not prevent neck hematoma formation".

Frequent advantages outlined by the participants included personal reassurance, possible prevention or early detection of hemorrhage, reduction in the incidence of seroma formation and reduction in postoperative pain and discomfort.

Measurement Parameter		Drain Group (n=112)	No Drain Group (n=100)
Age		49.32±11.6	47.35±10.77
Gender			
	Female	88.2%	83.5%
	Male	11.8%	16.5%
Diagnosis			
	Suspicious Solitary Nodule	60 (54%)	73 (73%)
	MNG Involving one lobe	31 (28%)	16 (16%)
	MNG	21 (19%)	11 (11%)
Histological Diagnosis			
	Benign Follicular Lesion	70 (62%)	64 (64%)
	Benign Hyperplastic Glands	21(19%)	13 (13%)
	Follicular Carcinoma	8 (7%)	14 (14%)
	Papillary Carcinoma	13 (12%)	8 (8%)
	Hashimoto's Thyroiditis	0	1 (1%)
Clinical Status			
	Euthyroid	74 (66%)	82 (88%)
	Hypothyroid	5 (4%)	4 (4%)
	Toxic Adenoma	33 (30%)	16 (16%)
ASA Status			
	ASA-I	100 (89.2%)	92 (92%)
	ASA-II	4 (3.5%)	4 (4%)
	ASA-III	5 (4.4%)	2 (2%)
	ASA-IV	3 (2.6%)	2 (2%)
Gland Size WHO Classification (1974)			
	WHO Class I	0	0
	WHO Class II	1 (0.8%)	7 (7%)
	WHO Class III	98 (87.5%)	82 (82%)
	WHO Class IV	13 (11.6%)	11 (11%)
Type of surgery			
	Lobectomy and Isthmectomy	91(90.1%)	87(87%)
	Total Thyroidectomy	21(9.9%)	13 (13%)
Mean length of surgery (minutes)		92.5±31.8	81.8±24.5

Table 2: General Patient Characteristics either having or not having drain

The representative statements have been outlined in the Table 1. Similarly, postoperative discomfort and potential lengthening of the hospital stay were considered as the potential disadvantages. One participant concluded by illuminating: "I think it is ok to put in a drain for 12-24 hours or so, it is not only reassuring for me but also reduces the incidence of postoperative seroma formation".

To further expand the findings of qualitative analysis and to put them to clinical perspective, we ran a randomized controlled trial. CONSORT protocol was followed and eventually 112 patients were randomized to drain group and 100 to the no-drain group. The general characteristics of the patients have been summarized in Table 2.

Measurement parameter	Drain group	No Drain group	P-value
Per-operative mean blood loss	39.86±24.75	42.95±25.06	0.135
Postoperative Drain Output	50.17±41.50	-	-
Mean length of postoperative stay (Hours)	25.91±9.87	21.82±3.57	0.773
Mean pain score (maximum = 10)	3.1±1.1	2.3±0.4	0.051*
Median postoperative analgesic requirements as per WHO pain ladder	Level II	Level II	0.341
Complications			
Wound infection	0.9%	1.2%	0.063
Hematoma requiring drainage	0.5%	0.9%	0.472
Seroma formation requiring drainage	1.4%	11.3%	0.000*
Transient hypocalcemia	0.9%	1.1%	0.936
Permanent hypocalcemia	0%	0%	-
Transient recurrent laryngeal Nerve compromise	2.8%	3.2%	0.265
Permanent recurrent laryngeal nerve compromise	0%	0%	-
Recurrence (Over period of at least 6 months-7 years)	0%	0%	-
Others (RTI)	0.3%	0.02%	0.634
Mean satisfaction with scar (maximum = 10)	7.9	8.3	0.640
Satisfaction with overall hospital stay (maximum = 10)	8.1	8.7	0.982

Table 3: Study endpoints summarized in both groups with and without drain

The primary endpoints included postoperative hemorrhage and neck hematoma formation, pain scoring, hospital stay and seroma formation (Table 3). Rest of the complications including hypocalcemia, recurrent laryngeal nerve compromise, recurrence over a period of at least 6 months and wound infection were also assessed.

Group without drain had significantly lower postoperative pain and discomfort as opposed to drain group (3.1±1.1 vs. 2.3±0.4; $p<0.05$) however postoperative analgesia requirement was not statistically different. Similarly, rate of seroma formation in postoperative period was significantly higher in the group receiving no drains (1.4% vs. 11.3%; p value <0.00). Despite a good quality hemostasis, average drain output was 50.17±41.50 ml in drain group probably forming the impetus for subsequent seroma formation.

Rest of the parameters like operative time, per-operative blood loss, hematoma requiring draining, would infection, postoperative hypocalcemia, RLN compromise and recurrence were not statistically different between two groups. Mean satisfaction with scar or overall hospital stay were not statistically different either (Table 3).

To explore the reasons of the higher seroma rate in no drain group, sub group analysis was done which showed size of the gland, extent of dissection and toxicity of the gland to be related to higher rates of seroma formation (Table 4). The size of the gland was the strongest predictor of seroma formation with Pearson Chi2 value of 11.99 and $p<0.002$.

In stage 3 of the study, the above data was shared in form of a report along with a proposed decision tree for the drain placement during thyroidectomy. The consensus was developed through 2 rounds on the decision tree with Fleiss's kappa value of 0.83. Figure 2, shows a proposed algorithm for the drain placement in thyroidectomy.

	Factor	Pearson Chi2 Value	Significance
1	ASA Status	0.759	0.859
2	Toxicity	4.289	0.04*
3	Fibrosis	6.634	0.07
4	Histological Diagnosis	5.963	0.11
5	Size of Gland	11.99	0.002*
6	Extent of Surgery	6.402	0.05*

Table 4: Subgroup Analysis: Factors Affecting Seroma Formation

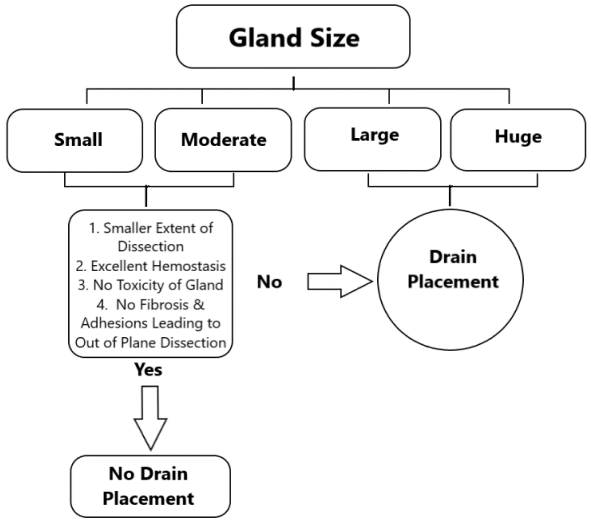

Figure 2: Proposed Drain Placement Decision Tree

DISCUSSION

Hematoma rates are generally low ranging from 0-2.6% and the ones requiring intervention are even less than 1.5%. Most hematomas develop in early postoperative period i.e. 75% within first 6 hours and rest in 6-24 hours[7,22]. Though the incidence of the hematomas is low but they can be potentially life threatening; thus, creating a reason for drain placement. Placement of drain though may be assuring for some, does not prevent the need for exploration if the patients really develop postoperative neck hematoma. Extensive literature review persistently shows that drain placement does not prevent hemorrhage [7,8]. Our study here further corroborates the findings of the previous literature and the incidence of postoperative hemorrhage without drains remains low. Contrary to evidence in literature stating that instituting drains following thyroid surgery may not prevent hemorrhage, quite a few of the surgeons still use drains for especially larger thyroid glands requiring extensive dissection. They feel reassured with drain placement citing four prominent reasons: firstly, most of the times following drain placement, even after quality hemostasis, some blood always pours into the drains; secondly, it gives a chance to pick hemorrhage early; thirdly it does reduce the incidence of postoperative seroma formation and fourthly it does not harm the patient even if nothing pours into the drain16. This 'conventional strategy' prevails among most of endocrine surgeons and may be coined as surgical wisdom by some [5,23]. Moreover, apprehension of bleed still persists among endocrine surgeons and their personal perceptions do play a role in the decision of drain placement.

Drain placement, however, does reduce the incidence of postoperative seroma formation and has thus been proposed to have selective use of drain by Saha et al [8,15]. This study further strengthens the literature evidence and propagates for placement of short-term drain for 12-24 hours as quoted by one endocrine surgeon in this study.

This study has explored the reasons for higher incidence of seroma formation whom did not have drain. Quality of hemostasis and expertise in securing hemostasis can be a significant factor in preventing postoperative hemorrhage as well as seroma formation[24]. The gland size and the extent of dissection exclusively correlate with higher incidence of seroma formation. Another reason could be related to toxicity and vascularity of gland. Friability and fibrosis of gland and adhesions may also be important influencers but they could not reach any statistical significance. The decision of using drain should be scientific and based on the factors which have been identified through this study and existing literature.

Instead of advocating no drains for all thyroidectomies, it appears prudent to commend for selective drainage following thyroidectomy. The algorithm, here proposed, promotes the decision of putting drain on the bases of quality of hemostasis, size of gland, extent of dissection and vascularity of gland. For large and huge glands (WHO Class IV and beyond), it would be probably be more prudent to place a drain as there would be higher chances of seroma formation and higher probability of life-threatening hematoma formation in neck.

There are certain limitations in this study. The study has primarily enrolled smaller and moderate size glands in clinical trial; hence the quantitative data is not sufficient enough to predict the rates of hemorrhage and seroma formation in those individuals. Moreover, qualitative data by principle is based on opinions and experiences and may not sufficiently prove exclusively that surgeon experience or perceptions are reflections of reality.

In conclusion, intent of earlier detection of hemorrhage, fear of postoperative hemorrhage and seroma formation were found to be the most common reasons for drain placement. The decision of placing a drain or not should be individualized and should correlate with extent of dissection, size of gland, quality of hemostasis, extent of adhesions either related to any inflammatory condition or malignancy and the vascularity of the gland. It remains safe to skip drain placement in small to moderate size glands provided the quality of hemostasis is superb and risk factors for seroma formation are not present.

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Archives of Surgical Research | Guideline Review

Grave's Disease: When to Jump for Operative Management?

Asif Hussain, Jawaria Avais

IMPORTANCE Thyrotoxicosis is mainly due to Grave's disease, toxic adenoma or multinodular goitre. Management depends on underlying etiology, patients age, patient's choices and comorbidities. Diagnosis of Grave's disease can be made clinically but often needs biochemical testing and imaging modalities. Additionally, pros and cons of various available treatment options for Grave's disease often helps for decision making. American Thyroid Association (ATA) has given very clear updated guidelines especially related to Grave's disease. This review is based mainly on the ATA guidelines to provide a summary of management for Grave's thyrotoxicosis.

KEY WORDS: Grave's disease, Grave's thyrotoxicosis, American Thyroid Association, Anti thyroid drugs, preparation for thyroidectomy

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Guideline Review

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Grave's disease (GD) is an autoimmune disease mediated by TSH receptor antibodies and is among the three most common causes of hyperthyroidism. 80-90% of thyrotoxicosis cases are caused by Grave's disease, toxic adenoma, and toxic multinodular goiter. GD can have ophthalmopathy and dermopathy as well, in addition to thyrotoxicosis. Rarely, GD can present as hypothyroidism. Less common causes of hyperthyroidism include various thyroiditis types (low uptake hyperthyroid), TSH secreting pituitary adenoma, exogenous ingestion of thyroid hormones, etc. The prevalence of thyrotoxicosis in the USA is 1.2% [1], whereas, in Pakistan, the prevalence of hyperthyroidism is 5.1%and is higher in females than males[2].

EVALUATION OF GRAVE'S DISEASE:

CLINICAL EVALUATION:

Complete evaluation of the patient, including hyperthyroidism symptoms, any underlying cardiac disease such as myocardial ischemia / atrial fibrillation/heart failure, neurological complication, or disease such as stroke/dementia, is essential. Cardiac assessment in those who are old (60 and above) or are at higher risk of cardiac disease may include ECG, echocardiogram, Holter monitor, and myocardial perfusion assessment. Still, it shouldn't be the reason to delay the treatment of thyrotoxicosis[3]. Also, thyroid-related review including size and cosmetic effect of any goiter, retrosternal extension, signs of thyroid malignancy such as lymphadenopathy / local compression of the adjacent tissues including trachea is an essential part of the evaluation[4].

BIOCHEMICAL TESTING:

Biochemical assessment includes TSH measurement alone for screening purposes. TSH is the most sensitive hormone to change when there is thyroid dysfunction in the adult population with an intact pituitary-thyroid axis. However, TSH may not be low in thyrotoxicosis cases if the underlying cause is a pituitary adenoma, thyroid hormone resistance syndrome, or the presence of interfering antibodies / heterophilic antibodies [5]. When clinical suspicion is high for thyrotoxicosis or for establishing the diagnosis, measurement of TSH along with free T4 and total T3 are needed. Measurement of free T4 & T3 is more valuable due to the protein binding of these hormones. However, free T3 assay isn't as robust, and hence total T3 is preferred. Total serum T4 (and sometimes T3) may be high without thyrotoxicosis in conditions such as high TBG (Thyroxine Binding Globulins) due to estrogen, pregnancy, hepatitis, porphyria, genetic X-linked trait of TBG, or drugs-related.

Similarly, genetically abnormal albumin (familial dysalbuminic), which has a higher binding affinity for T4, may also cause high T4 [6]. Many drugs such as Amiodarone, propranolol, Amphetamine also inhibit the conversion of T4 into T3 and cause high T4 levels. Free T4 can also be falsely elevated due to antibodies, displacement from albumin caused by protein binding drugs such as heparin, etc. Similarly, high biotin intake can also affect the hormonal measurement by interfering with the assays used [7].

WORK UP FOR THE ETIOLOGY:

Clinical assessment often helps to establish a diagnosis, mostly diffuse (GD) vs. nodular (TMNG, Solitary nodule), or tender thyroid (De Quervain's), Grave's ophthalmopathy

(GO), or Grave's dermopathy (GD) are helpful but often needs additional workup. Biochemically T3/T4 ratio will be low in thyroiditis or exogenous thyroxine intake. T3/T4 ratio will be high in thyrotoxicosis as hyperactive thyroid makes T3 more than T4. Thyroglobulin will be increased in thyroiditis and low if there is an exogenous Thyroxine intake[8]. Thyroid-stimulating hormone receptor antibodies (TR antibodies) are elevated in GD (rarely may be negative in mild GD) and also have prognostic value [9].

Thyroid uptake scans are often needed in thyrotoxicosis patients when TR antibodies are negative or the thyroid is nodular. Also, GD and nodularity can coexist where uptake scans will help to establish dual pathology. Diffuse uptake is seen in GD, patchy in TMNG, and single focus in TA. Uptake is low or absent in thyroiditis, exogenous thyroid hormone intake, or factitious thyroid disorders. Uptake in the neck will also be low or absent in Struma Ovarii. Pituitary related hyperthyroid will have high uptake in the thyroid. Iodine scans have more radiation risk than Tc pertechnetate scan. An uptake scan can also estimate radioactive iodine dose if chosen for the treatment [10]. However, uptake scans are not safe in pregnancy and lactation. Ultrasound Doppler measuring the blood flow will often help in such cases and shows hypervascularity in hyperfunctioning glands and can also help identify nodules. Suspicious nodules can also be biopsied under ultrasound guidance [11]. Painful thyroid gland with Tenderness on palpation, high ESR, and the low uptake on scans suggest De Quervain's thyroiditis. Post-partum thyroiditis often occurs within one year of the child's birth. The thyroid is painless, family or personal history of autoimmune thyroid disease is usually positive, and anti-TPO is positive [12].

TREATMENT OF GRAVE'S THYROTOXICOSIS:

BETA-BLOCKERS:

Propranolol is needed in almost all patients but especially those at risk of cardiac diseases. In those where non-selective beta-blockers are contraindicated, such as asthma or severe airway disease, selective beta-1 blockers such as Atenolol, metoprolol can be used. Cardiac calcium channel blockers such as Verapamil or Diltiazem can also be used if beta-blockers are not tolerated well [13].

ANTI-THYROID DRUGS (ATD):

ATD is preferred in patients who are not candidates for surgery, such as those with comorbidities, making them high risk for operative options or those who can't have radioactive iodine (RAI). ATD is also useful in GD where remission is likely such as small goiter, a low titer of TR antibodies, or mild GD. Pregnant or lactating females where RAI isn't safe and surgery also have risks are also managed preferably by ATD. Those with limited life expectancy, elderly, those who can't follow radiation precautions, failed previous RAI or surgical treatment, active Grave's Ophthalmopathy (GO), or where rapid disease control is needed are better treated with ATD [14]. Drug intolerance, young age, those with less likely remission of GD such as high titer of TR antibodies, nodular goiter, cosmetic issues with goiter, or large goiter with compression symptoms are not good candidates for drug therapy alone.

Propylthiouracil (PTU) has a higher incidence of side effects, especially hepatocellular injury, cholestatic jaundice, neutropenia, and skin rash when compared to Carbimazole (MMI), [15]. Also, PTU is short-acting with 2-3 doses / 24 hours, whereas MMI is a single daily dose. Hence carbimazole (in some countries like the USA, methimazole) is used preferentially. However, the placental crossing is less with PTU than MMI, and also PTU blocks the peripheral conversion of T4 into T3. These are the reasons why PTU is used preferentially in the first trimester of pregnancy and thyroid storm. PTU is also used if someone has minor adverse effects with MMI. Those with severe side effects with ATD or those who fail to become euthyroid with ATD should be considered for RAI or surgery[16]. Patients with GD are treated with ATD for 12-18 months and can be stopped once they are euthyroid, and TR antibodies are negative. Those who have positive TR antibodies after 12-18 months of treatment with ATD should be considered for alternative options. However, if alternative options are not available, ATD can be continued for the long term with regular monitoring of thyroid functions (TFTs) and TR antibodies, and ATD can be stopped when both parameters are normalized. Those who become hyperthyroid after completion of ATD should be considered for alternate therapy where suitable. Monitoring FBC and LFTs is essential at baseline and then regular intervals while the patient is on ATD, especially when they report any side effects[4].

RADIOACTIVE IODINE (RAI):

It's contraindicated in patients who can't follow precautions related to RAI, pregnancy or those who have a plan to be pregnant within the next six months of treatment, lactating mothers, those with thyroid cancer or suspected cancer of the thyroid or concomitant hyperparathyroidism. It's not a preferred treatment if there are suspicious nodules. Active Grave's Ophthalmopathy is also a contraindication for RAI. RAI is the right choice for those who want to avoid surgery, have previous neck surgery, have adverse events with ATD, have comorbidities such as cardiac issues, liver disease, periodic paralysis, or elderly. A pregnancy test should be done 2-3 days before using RAI, and contraception should be reassured for the next six months. It should be assured that other people are not at risk of radiations hazard by following precautions to avoid this risk.[17]

Patients should be started on beta-blockers and ATD (MMI) before starting RAI. MMI should be stopped 2-3 days before and then recommenced 5-7 days after the RAI, especially

for those who are at high risk of complications related to hyperthyroidism, such as cardiac patients. TFTs should be regularly monitored initially fortnightly and then 4-6 weekly till the first six months. Once patients are in the hypothyroid phase, Levothyroxine is started to maintain euthyroid status. Those with inadequate response to RAI can be considered for a repeat dose of RAI at three months [4.18].

SURGERY FOR GRAVE'S DISEASE:

Patients who are in the first or third trimester of pregnancy should be treated with ATD as surgery has high complications risks. It's relatively safe in the second trimester. Surgery is also avoided in cases where there are comorbidities such as cardiopulmonary, liver or renal disease, old frail patients, or where life expectancy is limited. Surgery is best for cases where there are nodules, suspicious nodules, risk of cancer, confirmed cancer, or associated primary hyperparathyroidism requiring surgery as well. Patients who have active GO or periodic paralysis are better managed with surgery [4].

The patient should be rendered as close to euthyroid as possible using ATD & beta-blockers before surgery to minimize the risk of perioperative complications, especially thyroid storm (TS)[19]. If emergency surgery is needed or ATD fails to achieve euthyroid status before surgery or the patient can't tolerate ATD, we need to use beta-blockers, corticosteroids, and inorganic iodine in the immediate preoperative period. Cholestyramine can also be added to promote fecal loss of thyroid hormones. Inorganic iodine such as Potassium Iodide (KI) is used 2-3 days before surgery as it helps normalizing thyroid functions and also reduces vascularity of the gland. Lugol's iodine is an alternative to KI. Vitamin D (calcitriol) and calcium replacement are needed as hypocalcemia is a common postoperative complication. Postoperatively ATD is stopped, and beta-blockers are slowly tailored. Levothyroxine is started after the operation, roughly at 1.6 microgram/kg. However, patients with cardiac history or at risk of cardiac disease are started at a lower dose. TFTs are monitored at regular intervals postoperatively to adjust the dose of the Thyroxine[4].

Total or subtotal thyroidectomy is performed, but the risk of recurrence is 8-10% with subtotal thyroidectomy, whereas recurrence is almost zero 0% with total thyroidectomy. The outcome is much better when the surgeon is experienced for these procedures[20]. Surgeons who perform more than 25 thyroidectomies in a year have a superior clinical and financial outcome, whereas the complication rate is almost 50% higher when the surgeon is less experienced. Experienced surgeons have less than 2% risk of permanent hyperparathyroidism and less than 1% risk of recurrent laryngeal nerve injury (RLN injury) [21].

A thyroid storm is a feared and dreadful complication that can happen, especially intraoperatively or postoperatively. It presents systemic decompensation, especially hyperthermia, cardiac, respiratory, hepatic, neurological, and renal complications. It can be precipitated by inadequate biochemical control, the stress of the surgery, or anesthesia. Thyroid storm should be avoided by aggressive monitoring, achieving euthyroid status before surgery (when possible), and the procedure carried out by an experienced thyroid surgeon[22]. It's assessed using Burch-Wartofsky Point Scale (BWPS) with a score equal to or > 45. BWPS score b/w 25-44 needs clinical judgment to manage. Other scoring systems, such as the Japanese Thyroid Association (JTA) or Thyroid Storm 2 (TS2), are less reliable. Caution should be practiced to diagnose thyroid storm in patients who don't have severe thyrotoxicosis as most of the manifestations of thyroid storm can also be seen in any significant illness such as sepsis etc., which are also triggers for the storm[23]. Thyroid storm is treated with combination therapy of ATD (preferably PTU), hydrocortisone, beta-blockers, intravenous fluid, cooling by paracetamol and cool blankets, cardio-respiratory support as needed, nutritional help, and monitoring in intensive care. Almost every step of hormone synthesis and action is blocked by combining these pharmacological options. Doses of the drugs used are much higher than regular doses; hence its significant to establish the diagnosis with certainty to avoid drug toxicity [4,23,24].

DISCUSSION:

Grave's disease can present in a wide range of clinical presentations from subclinical thyroid disease, thyrotoxicosis to thyroid storm. Rarely GD can coexist with Hashimoto's thyroiditis or can present as Grave's hypothyroidism. Diagnosis is often straightforward when it presents diffuse goiter and hyperthyroidism associated with Grave's ophthalmopathy and/or dermopathy and positive TSH receptor antibodies. However, an additional workup is often needed when the clinical, biochemical, and serological evidence is not conclusive. Uptake scans are not safe in pregnancy and lactating mothers, where ultrasound doppler often helps.

Decisions regarding further testing and management are guided by many factors, including age, sex, pregnancy/lactation, associated comorbidities, and patient preferences. Old frail patients with a lot of comorbidities are better managed with no-operative options. RAI is avoided in pregnancy, lactation, anyone with cancer or suspected cancer, and active GO. Surgery is the best choice when there is a possible or confirmed malignancy. If the patient is fit for a surgical option, total or subtotal thyroidectomy after achieving biochemical euthyroid status is the right choice when an experienced thyroid surgeon is available. Thyroid storm is a deadly complication that can be prevented and treated promptly in an ICU setup. Postoperative calcium management is an important aspect. Levothyroxine

replacement is needed after the use of RAI or surgical option. Post-op complications of permanent hypoparathyroidism and RLN injury is 1-2% in a high volume surgical set up for thyroidectomies.

	Onset Of Effect	Long Term Remission	Hypothyroid After Operation	Advantages	Disadvantages	Patients Factors Favoring The Treatment Option
ATD	2-4 weeks onset Most achieve euthyroid in 8-12 weeks	30-50%	15-20% over many years	Non invasive Cheaper Outpatient No preparation needed. No worsening of GO Low hypothyroid risk.	Side effects Low remission rate Compliance & monitoring issues	Poor surgical and RAI candidates. GO Pregnancy and lactation High remission chances
RAI	4-8 weeks. Most achieve euthyroid in six months	75% in 6-12 months	Almost 50% in one year and increases with time.	Cost effective Outpatient Few sides effect Reduced goitre size Can be used in those with comorbidities	Radiation risk and precautions. Needs to delay pregnancy. Worsens GO in 15-20%. Permanent hypothyroidism risk. Transient worsening of hyperthyroidism	Low chance of remission Poor surgical candidates and/or contraindications to ATD.
Surgery	Immediate	Almost 100%	Almost 100%.	100% effective and immediate effect. No worsening of GO Removes any suspicious nodule / cancer, associated hyperparathyroidism treatment also. Recurrence is very low.	Surgical complications (RLN injury, hypoparathyroidism) and surgical scar. Costly and inpatient Permanent hypothyroidism Not safe with other comorbidities.	Thyroid cancer or suspicious nodules. Associated hyperparathyroidism Pregnancy and lactation when ATD don't work. Active GO. Large goitre, cosmetic reasons or compression symptoms.

Table 1: Comparison of various treatment options for Grave's Thyrotoxicosis.

Abbreviations: ATD (Anti thyroid drugs), GO (Grave's Ophthalmopathy), GD (Grave's Disease), RAI (Radioactive Iodine). Comparison of various therapeutic modalities for Grave's Thyrotoxicosis [25].

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Archives of Surgical Research | Original Investigation

Recent Healthcare Information Breaches and Their Lessons

Haroon Elahi, Oana Geman

IMPORTANCE Modern health facilities are continually reporting data breaches, which raises the need to understand underlying factors and design mitigation strategies accordingly.

OBJECTIVE The objective of this research is to analyze real healthcare data breaches, identify underlying factors, and report the lessons that may help in preventing the future breaches.

DESIGN This study is based on exploratory analysis of electronic health record breaches reported to the U.S. Department of Health and Human Services, Office for Civil Rights during the past twenty-four months (December 2018 - December 2020).

DATA SOURCES This study uses the data of breaches reported within the last twenty-four months, and currently under investigation by the Office for Civil Rights and provided, obtained from the breach portal of the U.S. Department of Health and Human Services, Office for Civil Rights. These breaches affected more than 42 million individuals.

METHODS: We analyze 698 breach cases affecting more than 42 million individuals to identify underlying attack patterns, trends, outliers, and unexpected results, and major factors leading to these breaches in recently reported electronic health record breach cases.

RESULTS The frequency of data breaches reported during the past twenty-four months shows an increasing trend; their overall impact size is consistent, with a few exceptions. The most significant data breaches involved business associates, healthcare providers, health plans, and healthcare clearinghouses, with healthcare providers and business associates impacting about 83% of the affected individuals' privacy. However, most breaches occurred at smaller entities. Hacking of emails and network servers are the most common breach types, followed by unauthorized access, theft, improper disposal of records and devices, and loss.

CONCLUSION The nature and size of the incidents suggest paying particular attention to human factors, small-sized healthcare entities, business associates, and continuous revision of related security standards and frameworks.

KEYWORDS: Security attacks, Data breach, Electronic health records, Human factors

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Original Investigation

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Computing-based health information technology (HIT) systems and electronic health records (EHRs) target to improve the overall healthcare system by enabling efficient data sharing among different healthcare system stakeholders [1]. The confidentiality and accuracy of the EHRs and HIT systems' security and reliability are prerequisites for building users' trust in these systems, particularly patients whose information is collected, processed, stored, and transmitted by these systems. Since this information includes sensitive data that, if exposed, can have severe implications for the data subjects and the health service providers, new privacy and security issues are arising [2].
For example, on the one hand, easy access to this information by different HIT stakeholders improves the healthcare delivery system. Still, the exposure of this information can affect the patients' insurance, career, or relationships. Various malicious parties can try to access and use this data for illegal gains and purposes, e.g., for blackmailing healthcare providers for money.

Due to healthcare's central role in society, any disruption due to the unavailability of EHRs or discontinuity of HIT services can be considered a worst-case scenario to topple a society. Therefore, in recent years, a rise in the number of cyber-attacks against healthcare systems has been observed. Recently, the president of the International Committee of the Red Cross warned about the increasing frequency of malicious attacks against hospitals and other

critical public infrastructural facilities [3]. "If hospitals cannot provide life-saving treatment in the middle of a health crisis or an armed conflict, whole communities will suffer," he explained in a meeting of the United Nation's Security Council.

Considering the sensitivity of the data processed by HIT systems, organizations like the National Institute of Standards and Technology (NIST) and the European Commission have issued special guidelines for managing electronic health records [4–6]. Likewise, dedicated security frameworks have been introduced for installing and operating HIT systems and exchanging EHRs [7].
Consequently, we see that special attention has been paid in recent literature to investigate the privacy and security issues of HIT systems and relevant infrastructures [8–11]. These researches identify the security requirements for setting up HIT systems, the nature of privacy and security issues in these systems, and internal and external attack vectors for pre-emptive security.

However, modern health facilities, equipped with sophisticated medical devices and computing systems recording and efficiently exchanging patient data and various health information with different stakeholders to deliver superior services, are continually reporting data breaches. This introduces the need to identify underlying factors contributing to these breaches for effective security. One of the approaches is to use automated risk detection models and designing and implementing different controls to mitigate these risks. But recent research proposes that many of the automated risk detection models designed for HIT systems and related infrastructural facilities are faulty [12].
Furthermore, due to the continually evolving nature of cyber threats, we need to look at privacy, data protection, and security in a completely new, fresh way and adapt our activities to the afresh cyber reality [13]. The objective of this research is to analyze real healthcare data breaches, identify underlying factors, and report the lessons that can help in mitigation.

RELATED WORK

The Healthcare system comprises of different players, including but not limited to sickness funds, hospitals, laboratories, etc., who need to communicate health data for treatment and other purposes [4]. A modern HIT system may process clinical information, handle telemedicine, or offer personalized care services or remote patient monitoring services. It can include teleconsultation and teleradiology. It integrates health information networks, distributed EHR systems, e-prescriptions, e-referral, etc. The nature of the processed data, the distributed nature of infrastructure facilities, and the variety of actors introduce unique privacy and security concerns [14]. Many researchers have investigated these issues and their implications.

Shoniregun, Dube, and Mtenzi [15] proposed that the increased privacy and security concerns among the general public led to the development of different legal frameworks for information protection in HIT systems. They proposed that laws and standards stipulating IT security adoption and sanctions for non-compliance were common features in securing HIT systems. They further proposed that effective compliance could only be achieved by putting different security and privacy controls in place.

Wuytz [2] focused on data privacy issues in HIT systems. They proposed that an analysis of the privacy issues emerging from integrating EHR, PHR (public health record), and community data should be the first step towards implementing HIT systems. They proposed a taxonomy for classifying health data into different categories for better access management. They suggested that access control in HIT systems could be achieved by defining different access levels and corresponding access rights.

Zeadally et al. [10] conducted a study to explore the underlying possibilities of security and privacy risks for HIT systems, discussed security attacks reported during the first six months of 2016 for these systems, and proposed different solutions to mitigate these attacks. They also identified future challenges for achieving end-to-end security and privacy in HIT systems and associated these challenges with integrating various emerging technologies. However, they focused only on deliberate attacks intended to compromise information security and privacy and further narrowed down their study to only three specific domains: body area, communication infrastructure, and service.

Mcleod and Dolezel [16] modeled different exposure, security, and organizational factors to determine their associations with healthcare data breaches. They found that increased connectivity of healthcare facilities meant increased exposure and higher chances of data breaches. They found that somehow laboratory barcoding was related to an increase in the data breach chances. Establishing an association with business associates with vulnerable computing systems was also recognized as a factor that could lead to data breaches. They also discovered that healthcare facilities with complex structures were at great risk of experiencing data breaches. Finally, they associated the spending on HIT systems' security with data breaches: the lower the spending, the higher the chances of a breach.
Keshta and Odeh [8] performed a review of literature to identify the privacy and security concerns in HIT systems and to examine the solutions that could address the identified concerns. They found that recent research identified physical, technical and administrative factors as major causes of potential security and privacy threats in HIT systems.

Niazkhani et al. [17] conducted a review of recent original studies assessing barriers to EHR adoption/use in chronic care. They discovered that these systems privacy and security concerns were significant barriers to the adoption of HIT systems.

Hoffman et al.[13] identified six types of vulnerabilities for the security and privacy of a computing system. They proposed there could be vulnerabilities lying in legislation gaps, human factors, organizational structures, processes, technical implementations, and physical protection of the system.

Despite that these past studies make valuable contributions, due to the continually evolving nature of cyber threats, we need to look at privacy, data protection, and security in a completely new, fresh way and adapt our activities to the afresh cyber reality [13]. This research aims to analyze real healthcare data breaches, identify underlying factors, and report the lessons that can help in mitigation.

METHODS

We analyzed data consisting of 698 cases of real data breaches reported to the United States Department of Health & Human Services. We obtained the data for this study from the official breach portal of the United States Department of Health & Human Services. The data consisted of all under investigation breaches reported within the last 24 months beginning from 17th of December 2018 till 14th of December 2020.

DATA DESCRIPTION

The analyzed data consisted of 698 cases of data breaches reported by four different types of covered entities. Each case contained information on the name of the covered entity, covered entity type, the number of individuals affected, breach submission date, type of breach, location of breached information, and business associate presence. The covered entities included business associates, health plans, healthcare clearinghouses, and healthcare providers. These entities were all located in different parts of the United States of America.

The reported breaches included hacking/IT incident, improper disposal, theft, loss, and unauthorized access/disclosure. These breaches' locations included desktop computers, laptops, network servers, emails, electronic health records, paper films, other portable devices, and other.

PROCEDURE

An exploratory data analysis was performed. Exploratory data analysis aims at classifying behaviors within a given area of research, identifying potentially important variables, and identifying relationships between those variables and the behaviors [18]. We downloaded the data in Microsoft Excel format. We explored and analyzed data using SPSS and Microsoft Excel tools. Certain data pre-processing was needed, particularly in the case of the location of the breached information.

In many cases, more than one location was involved. We used Microsoft Excel functions to sort individual locations for finding the role of individual locations of the data breaches. We used Microsoft Excel tools like built-in functions, pivot tables and graph builder to generate tables and graphs. SPSS was used to generate descriptive statistics for making sense of the data.

RESULTS

Figure 1 shows an overall increase in the number of reported breaches over the past 24 months. However, a sharp decrease in the number of attack frequencies can be observed in October,

November, and December of 2020. The figure shows that the lowest numbers of breach reports were made in December 2018, and the highest numbers of breaches were reported in September 2020.

Figure 2 shows the month-wise distribution of the number of affected forty-two million individuals. It can be seen that July 2019 was the most damaging month when more than 12 million individuals were hit by data breaches involving their medical data.

Entity type	Number
Business Associate	79
Health Plan	57
Healthcare Clearing House	2
Healthcare Provider	560
Total	698

Table 1: Breakup of the reported breaches according to the types of reporting covered entities

Entity Type	Number of Affected Individuals
Business Associate	15,927,846 (38%)
Health Plan	5,473,369 (13%)
Healthcare Clearing House	1,611,070 (4%)
Healthcare Provider	18,990,233 (45%)

Table 2: Distribution of number of affected individuals according to covered entity types

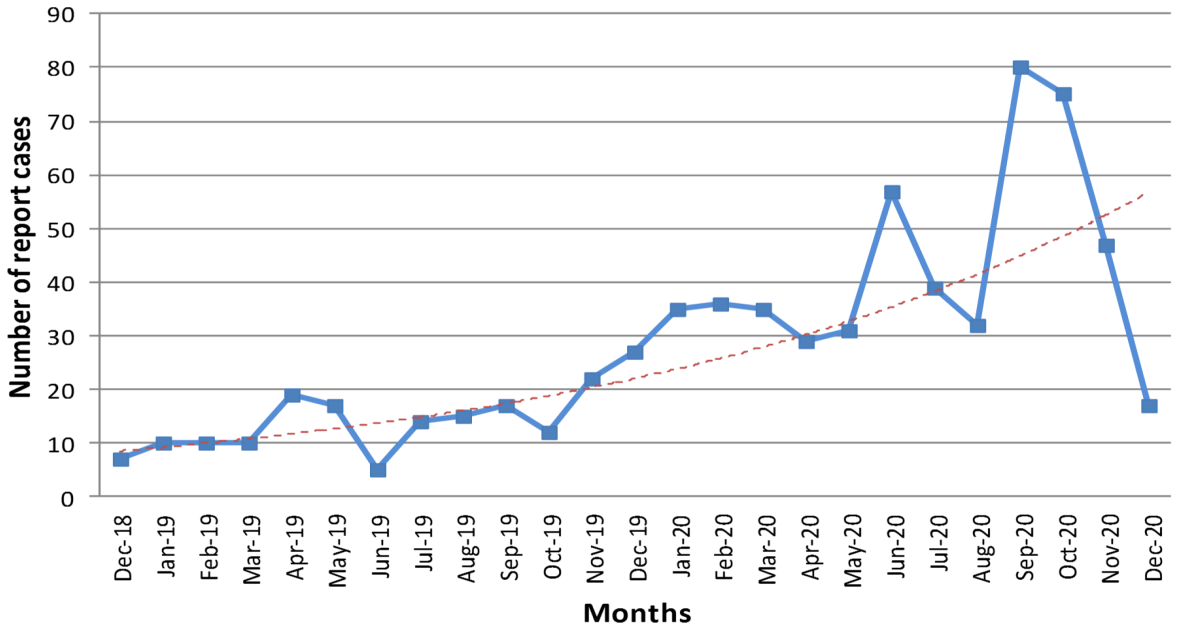

Figure 1: There is an overall increase in the number of reported data breach cases in the past 24 months.

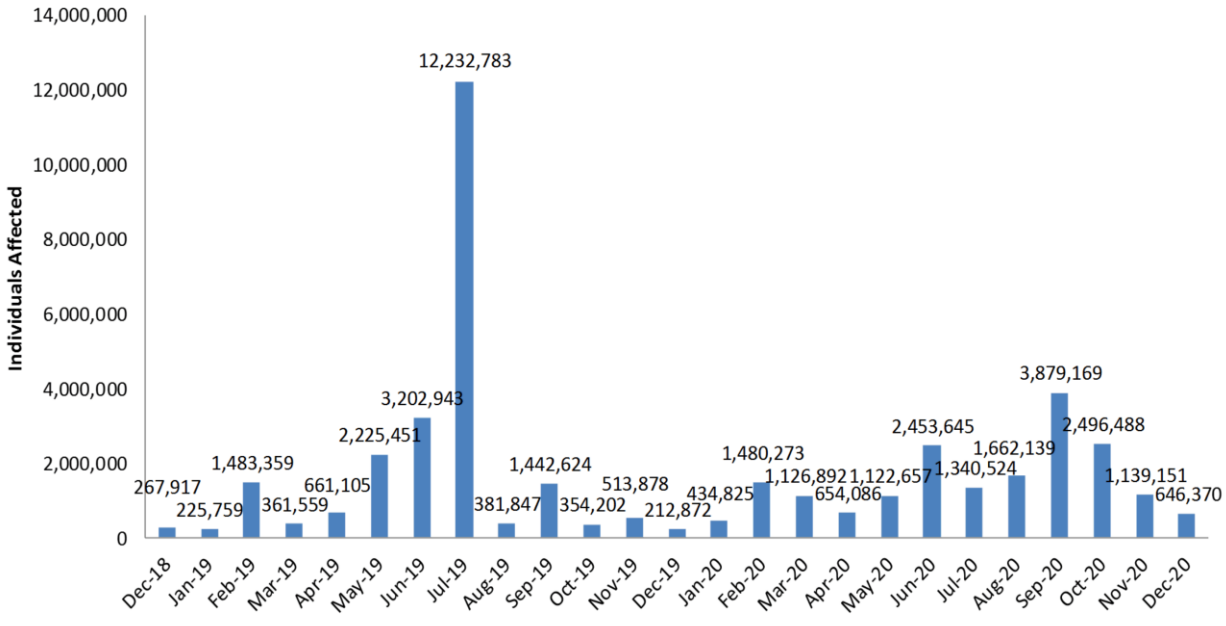

Figure 2: Month-wise distribution of the number of affected individuals

Table 1 shows that among the 698 cases, healthcare providers reported about 80% of the breaches. However, looking at the number of individuals affected by breaches, as shown in Table 2, although the number of breaches reported by the business associates was significantly lower than those reported by the healthcare providers, these breaches affected a large number of individuals. Table 3

shows the further breakup of the impact of breaches on individuals according to incident types.

Entities and Incidents	Sum of Individuals Affected
Business Associate	15927846
Hacking/IT Incident	15774406
Loss	6723
Theft	23394
Unauthorized Access/Disclosure	123323
Health Plan	5473369
Hacking/IT Incident	4627773
Theft	656020
Unauthorized Access/Disclosure	189576
Healthcare Clearing House	1611070
Hacking/IT Incident	45732
Unauthorized Access/Disclosure	1565338
Healthcare Provider	18990233
Hacking/IT Incident	17092365
Improper Disposal	571535
Loss	172766
Theft	135041
Unauthorized Access/Disclosure	1018526
Grand Total	42002518

Table 3: Breach types affecting different entities and the numbers of affected individuals

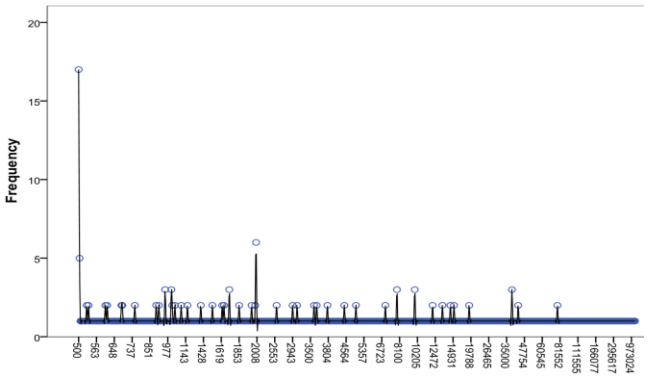

Figure 3: Frequency distribution of breaches according to number of affected individuals

Table 3 shows a total of forty-two million individuals were affected by the breaches analyzed in this study. It presents the distribution of the number of individuals affected across the four types of covered entities.

Figure 2 shows the frequency distribution of breaches according to the number of affected individuals. It is clear from the figure that most of the breaches affected less than 5000 individuals each. Notably, the frequency of breaches affecting 500 individuals is very high.

Tables 4 shows the distributions of the number of affected individuals in cases where business associates are present or absent. It is learned that although a little less than half of the cases involved business associates.

Row Labels	Sum of Individuals Affected
Business Associate	15927846
Yes	15927846
Health Plan	5473369
No	4634925
Yes	838444
Healthcare Clearing House	1611070
No	1611070
Healthcare Provider	18990233
No	12873960
Yes	6116273
Grand Total	42002518

Table 4: Distribution of affected individuals in the presence or absence of a business associate

Incident Locations	Hacking	Improper Disposal	Loss	Theft	Unauthorized Access
Email	250	0	0	0	39
Desktop Computer	22	1	0	8	3
Laptop	4	1	0	15	5
Network Server	250	0	1	2	16
Electronic Medical Record	15	0	1	1	28
Paper/Films	0	12	3	17	38
Portable Devices	1	0	7	8	4
Other	26	0	2	2	11

Table 5: Breach locations and corresponding incidents

More than half of affected individuals come from cases where there were not business associates present. However, looking at the total number of business associates in Table 1, it can be observed that despite making up only 11% of the total covered entities that reported the breaches, the total number of individuals affected due to these breaches is very high.

Table 5 lists the locations where the breaches occurred, the types of the incident leading to breaches, and the respective incidents. The major incidents leading to data breaches were hacking and unauthorized access and mostly involved emails and network servers. Hacking-based breaches made about 71% of the overall reported incidents. Among these 91% hacking incidents involved

emails and network servers. Desktop and laptop computers and other portable devices like smartphones or USB storage devices can also become a means of breaches.

Data shows that desktops and laptops were almost equally affected by the hacking, theft, and unauthorized access. However, in the case of laptops, theft was a major reason for the potential data breach. Surprisingly, paper/films became a source of data breaches in 70 cases and were subject to unauthorized access, theft, improper disposal, and loss. In forty-three cases, other factors were also involved. They can include hacking and unauthorized access.

DISCUSSION

This paper analyzed 698 cases of healthcare data breaches reported to the U.S. Department of Health and Human Services, Office for Civil Rights during the past twenty-four months (December 2018 - December 2020) with an aim to identify underlying factors and report the lessons that can help in mitigation. The analysis showed an increasing trend in the number of reported breaches during the past 24 months. In the presence of a large number of security and privacy guidelines for the healthcare IT systems [4,7,9,15], it is an alarming situation.

Previous research shows that privacy and security concerns of the healthcare data led to the development of security standards and regulatory and security frameworks for these systems [15]. These frameworks need to be reviewed, keeping in view the emerging threats. More efforts should be put into compliance audits to ensure that entities handling the healthcare data are sticking to regulatory guidelines and standards.

The analysis showed that healthcare providers were most frequent in reporting breaches among different stakeholders of the healthcare systems. However, despite being a less frequent target, healthcare system business associates experienced data breaches whose impact size was comparable to those of the far larger numbers of healthcare providers. Previous research has associated these entities with the vulnerabilities of HIT systems[16]. We assume that these business associates can have associations with multiple healthcare providers and, therefore, bigger databases with a larger number of electronic health records and patient personal data. Dedicated security standards and guidelines should be developed for these entities.

It was also discovered that the majority of the breaches involved data of less than 5000 individuals. It can be that smaller entities pay less attention to their security infrastructures due to limited budgets and become an easy target of hackers. Or due to less investment in training their employees in cybersecurity, these entities fail to develop an organizational culture that ensures following the security best practices [16]. Effective security frameworks with low budgetary requirements need to be developed for small size entities. Mandatory online security training can be one effective solution to improve security awareness and security skills of HIT systems users.

The major incidents leading to data breaches were hacking and unauthorized access and mostly involved emails and network servers. While exploiting emails depicts a lack of following security practices among email users, professionals manage network servers. Past research shows that network security hacks mainly result from IT infrastructure mismanagement [19]. However, the role cloud service providers and vulnerabilities in the underlying platforms should also be determined. The specifics of the HIT systems should not be ignored in this process [20].

Previously, different models have been proposed to address the issues resulting from unauthorized access [2]. Integration of new technologies such as cloud computing-based infrastructures redefines the systems' trust boundaries, and therefore, new models are needed to manage access. Similarly, to avoid the theft of equipment carrying healthcare data, bring your own device (BYOD) culture should be discouraged in the cases where a user handles the data. Likewise, mobile access to these systems should be restricted as these devices can be easily stolen or lost. Improper disposal of health records is one of the factors leading to data breaches in healthcare systems. The data shows that the number of incidents involving improper disposal of records is low and can be controlled through effective disposal policies such as mandatory in-house record disposal.

Finally, previous research has focused on technical and organizational aspects of security issues in HIT systems [8,10,16]. The nature of incidents like hacking, unauthorized access, improper disposal, and theft requires investigating the human factors' role. Extensive field studies need to be conducted in this regard. In this regard, our findings are in line with those of [13].

LIMITATIONS

This study is based on the data comprising healthcare data breaches that occurred and reported in the United States. However, similar technical infrastructures and used to support healthcare facilities across the globe. It is also evident that most of the incidents are driven by the skill and awareness of the healthcare systems' users/operators. The disparity among the levels of these skills in different countries is known [21] and should be considered.

CONCLUSION

In this paper, we performed an exploratory analysis of 698 cases of data breaches reported to the U.S. Department of Health and Human Services, Office for Civil Rights during the past twenty-four months (December 2018 - December 2020). We found an increase in the frequency of incidents involving healthcare data breaches. We understand that there is a need to continually reviewing the existing security frameworks, developing dedicated security standards and performing stricter security audits for business associates, developing security frameworks

keeping in view the capabilities of small-sized entities, and mandatory online training for the users of HIT systems. Furthermore, with the involvement of technologies like cloud computing, special access control measures need to be developed. We observed a prominent role of the human factors in the data breaches. Extensive studies are required to identify the underlying factors and develop procedural and usability improvements.

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Archives of Surgical Research | Commentary

Approach Towards Breast Reconstruction Using Latissimus Dorsi Flap

Muhammad Jibran Rabbani, Asif Zubair Bhatti, Ahmed Shahzad, Sarah Rabbani

IMPORTANCE Latissimus dorsi flap is well recognized reconstructive option for postmastectomy breast reconstruction. It is a broad muscle that can cover a large area, can give volume, and can be used for coverage of inferior pole of breast implant. It can also be used as a salvage procedure especially in case of failed previous attempt. Moreover, it provides well vascularized cover on previously irradiated tissue. This article will review uses and advantages of pedicled latissimus dorsi flap.

KEYWORDS: Breast reconstruction, Latissimus dorsi flap

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Commentary

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Complete management of breast cancer patients also includes breast reconstruction, which proves to be a key component. Restoration of natural appearance of the breast is the major goal of breast reconstruction that improves the quality of life after post cancer mastectomy. Breast reconstruction may be by autologous tissue, implant, or combination of both. Overall, trends towards implant-based reconstruction are increasing with a ratio of 9:1 as compared to autologous tissue reconstruction.[1] The choice of procedure to be opted is multifactorial. This trend may be attributed to patient factors like nonavailability of donor tissue, co-morbidities, which may preclude the use of autologous tissue, donor site morbidity, and above all, patient preferences. Other factors considered include more operative time, exceptional surgical skills and training, availability of specific instruments, and more resources. [2,3] Undoubtedly, use of autologous tissue obviates the risk related to implant-based surgery including implant infection, rupture or contracture of implant and its dislodgement and migration. Implants are avoided in cases where postoperative radiotherapy is to be given or has already been given as a part of breast conservation therapy.[4,5] It has been observed that long term quality of life is better in patients who underwent autologous reconstruction.[6]

Immediate breast reconstruction is always a preferred method by most patients, but its decision depends on many factors. Combination of autologous tissue and implant can be done as single stage or two stage with the use of tissue expander and later replaced with a permanent implant. Skin sparing surgeries, being proven ontologically safe,[7] provides ample tissue for implant coverage, but additional tissue may be needed to provide adequate tissue and also to create a good mound. Provision of additional tissue may decrease implant-based complications like capsular contracture, rippling, and implant migration. Pedicled as well as free tissue transfer has been described in the literature for breast reconstruction that includes latissimus dorsi flap (LD), rectus abdominus flap (TRAM), free deep inferior epigastric artery perforator flap (DIEP), superior and inferior gluteal artery perforator flaps (SGAP, IGAP) etc.

Introduced in 1906 by Iginio Tansini,[8] latissimus dorsi (LD) flap was used for anterior chest wound coverage and was later used in 1912 by Stefano d'Este for the reconstruction of defect created after mastectomy.[9] Schneider et al., in 1977, described in detail the anatomy of this flap and used it in implant-based breast reconstruction in a young lady who had a mastectomy four years ago. He found this flap useful in providing supple skin coverage while creating a natural breast mound. Since then, latissimus dorsi flap has been considered a viable breast reconstructive choice for partial or total mastectomy.[10,11] Ease of harvest and consistent vascular pedicle of this flap has favored its existence and success and popularity among reconstructive surgeons.[12-14] Literature testifies its utility in both immediate and late reconstruction.[12-15] Many plastic surgeons, after the advent of perforator flaps and identification of perforators of the thoracodorsal artery, have started to spare the muscle in order to preserve its function and to avoid the morbidity associated with muscle sacrifice. [16,17] However, the use of latissimus dorsi muscle has been advocated in many circumstances like in case of previous reconstructive failure[18], prior radiotherapy[19], implant failure[20], and recurrent cancer after breast conservative therapy. [21] Other benefits of using this flap in delayed reconstruction include fewer complications, no need for microvascular skills, and it can provide vascularized coverage of previously irradiated chest.[22,23]

LD flap can be used for immediate breast reconstruction or in delayed cases in a single stage or two stage fashion on surgeons' and patients' choice and preferences. After

mastectomy, if no reconstruction is to be done, LD flap can be used for wound coverage in cases where ablative surgeon is not able to close the mastectomy defect primarily. If breast reconstruction is opted, latissimus flap is inspected, and other donor sites like TRAM, DIEP, SGAP, IGAP should be explored. LD flap is chosen in case of nonavailability of other optimal options, large skin defect with an open wound, prior reconstruction failure, and prior infection. Then the choice is made, if LD flap is to be done alone or with an implant that can be single stage with a permanent implant or two stages with expander-implant procedure depending on patient condition like presence of open wound or infection and whether the patient is to under radiotherapy after the surgery. [24]

The inherent problem in breast reconstruction is to get good aesthetic results, especially in single stage procedure. The problem lies in obtaining muscle coverage over inferior pole of implant and to create adequate ptosis while making a proper definition of inframammary fold.[25,26] Even in subpectoral implant placement, there is scanty tissue for coverage of the lower pole of the implant, and the implant is only partially covered, which may increase the risk of complications, poor projection, and implant loss.[27-29] It is not easy to achieve good symmetry in one procedure. Therefore, some surgeons prefer two stage breast reconstruction with expander.[27] Fascia of rectus abdominus muscle or use of serratus anterior muscle for coverage of inferior pole has been described to achieve good definition of inframammary fold and lower pole fullness.[26,30] Use of latissimus muscle flap was reassessed but was found to be insufficient to provide adequate volume alone.[10] If the muscle is used along with the implant, sufficient volume can be achieved while providing good soft tissue coverage over the inferior pole of the implant and thus gaining good results.[31] Studies showed that if latissimus muscle is used along with implant, either one stage or two stage, good volume, better definition of inframammary fold, and adequate ptosis can be achieved.[32] Harvesting of LD flap allows the surgeon to create a pocket large enough to accommodate permanent implant, thus obviating the need for tissue expander placement.[33,34]. Other than cosmetic benefits, transfer of well vascularized tissue is preferred in already irradiated chest wall.[35-37] It is established that reconstruction quality is improved if nonradiated tissue is transferred to the irradiated area. [36,37] One concern is functional impairment after use of latissimus dorsi, but it is well documented that it is an expandable muscle, and its use does not create considerable functional loss at the shoulder. Long follow up studies had not reported any significant functional or strength impairment after sacrifice of latissimus dorsi muscle other than mild functional limitation in case of extreme physical activity.[38,39] Another challenge is harvesting of big skin peddle with muscle leaving a significantly large wound that is to be closed primarily having increased risk of wound dehiscence or cosmetically unacceptable hypertrophic scar.[31,35,36] This can be overcome by good preoperative planning. Some studies have proposed to take minimum skin island that should be used for nipple creation later on as large skin paddle may not have good cosmetic results at recipient area.[33,40] Another consideration is patient repositioning during the procedure that increases the operative time. Muscle is not usually denervated in fear of muscle volume loss.

Use of latissimus dorsi flap for breast reconstruction, either in single stage, two stage or three stage procedure, is best indicated where abdominal flap (free or pedicle) is not available or possible, where previously failed free flap has been attempted, and there is nonavailability of donor vessels, where other free flaps options are not available, in case of chronic chest wall wound and the patient is not willing to have formal breast reconstruction, in patients with wound infection, in patients with implant infection and explantation and in case of severe radiation injury to the chest wall. LD flap may be used as a salvage procedure. Above all, surgeon and patient preferences should be taken into account. However, this procedure does not preclude the necessity of secondary procedures like fat grafting and symmetrizing procedure on the contralateral breast. [24]

Patient counseling is an integral part of any procedure. In the case of breast reconstruction with LD flap, the patient is explained about the donor site, donor and recipient site scars, surgical wound related complications. The postoperative course is explained, including dressings and drains. Expander or implant related issues should be discussed in detail. On average, patient remains in the hospital for 2 to 3 days. Upper limb range of motion exercises are started after two weeks, and regular activity is expected to be regained in 3 to 6 weeks. In the case of expander placement, expansion is started at two weeks postoperatively. [41]

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Archives of Surgical Research | Original Investigation

Quality Assurance Of Online Surgical Learning Process: Development and Validation of Shalamar Online Learning Experience Measure (SOLEM)

Fatima Tuz Zahara; Zaitoon Zafar; Talat Waseem; Hasan Shoaib

Original Investigation

IMPORTANCE The COVID-19 pandemic has strained medical infrastructure, stagnated global economy and disrupted student life worldwide. The need for social distancing presented a unique challenge to surgical educators, and schools took the opportunity to become virtual, medical students learning surgical techniques in particular were required to take clinical instructions online. This also presented another challenge for the educator— quality assurance of the online learning process.

OBJECTIVE In this study we have developed and validated an online learning instrument, namely Shalamar Online Learning Experience Measure (SOLEM), which would serve as a standard against which quality assurance of online learning programs, particularly of surgery, could be established and maintained.

METHODS Using previously validated questionnaires assessing various dimensions of learning along-with necessary modifications, we designed a comprehensive instrument (SOLEM) to gauge parameters of student cooperation, teacher support, resource adequacy, computer usage, active learning, design and appeal, order and organization, reflective thinking, and lastly, of perception (of self, of teacher, of atmosphere and of learning). This newly designed instrument was expert validated for relevance and content validation and was finally piloted to run Exploratory Factor Analysis (EFA) for determining reliability, internal consistency and construct validity.

RESULTS Following an expert validation from eight experts, a total of 162 participants completed the questionnaire. The final version of the SOLEM has 48 items allocated to 12 scales. Cronbach's alpha for the overall questionnaire was 0.921. The alpha reliability coefficient for each subscale ranged from 0.776-0.912. The output of EFA revealed that each representative learning item had a factor loading of at least 0.50 with its own scale, thus adding to the overall construct validity of the questionnaire.

CONCLUSION & RELEVANCE Newly designed 48-item Shalamar Online Learning Experience Measure (SOLEM) is a valid, reliable and efficient method to measure medical students' perception and test the quality assurance of an online learning experience in a surgical setting and may be generalizable to other online educational programs as well.

KEYWORDS Learning experience; Online education; Questionnaire development; Surgical learning; E-learning; quality assurance of online learning, quality assurance

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In order to contain the ongoing pandemic brought on by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), all instructions from governing bodies point towards social and/or physical distancing as a non-pharmaceutical intervention for infection control, intended to slow the spread of disease by minimizing close contact between individuals [1] [2] [3]. Social/physical distancing is defined by the American CDC as "keeping a safe space between yourself and other people who are not from your household" [2]. The CDC recommends a distance of 6 feet (1.8 meters) [2] while the WHO recommends a distance of 3 feet (1 meter) [3]. Such measures have presented a special challenge to people worldwide, but especially to educational institutes, for whom it will be most difficult to maintain social/physical distancing rules. According to UNESCO, the pandemic, at its peak in April 2020, caused almost 200 countries to completely close their schools, with more than 1.5 billion students affected [4].

Educators have taken the task in stride and have turned to the internet to ensure their students' precious time is not wasted. The predicament is particularly worrisome for students in the medical sciences, who have had to take clinical instruction usually available in a hospital or clinic setting in their final years, on webinars and Zoom sessions.

This transitioning of mass schooling to virtual screens is a solution to social distancing that would not have been possible more than a decade ago and hence is a situation that has presented itself for the first time. Resultantly, there is a gap of knowledge in regards to the effectualness, strategies necessary for, and shortcomings of an online education. With our study at Shalamar Medical and Dental College, Lahore we have tried to bridge this gap. Our study especially dealt with medical students who had to take necessary instructions online.

The college, based in the metropolitan city of Lahore, Pakistan, wasted no time in introducing Shalamar e Learning Management System (SeLMs)—a Moodle based application, Webinar Jam and Surgiomics (a collection of web resources for the students) for online learning. Daily lectures were broadcasted live to students of all years (Year 1 through 5 of MBBS), with clinical wards and operative procedures being taught live to students in Year 3 through Year 5. Subsequent assessments were taken on the SeLMs in the form of Multiple-Choice Questions (MCQs) and Short Essay Questions (SEQs).

To evaluate the efficiency of the virtual learning set up, the Shalamar Online Learning Environment Measure (SOLEM) was developed. This article begins with foundation information about learning environment research, next the phases in the turn of selection of scales and items of SOLEM questionnaire. The article at that point moves to expert validation and pilot validation of the newly developed questionnaire.

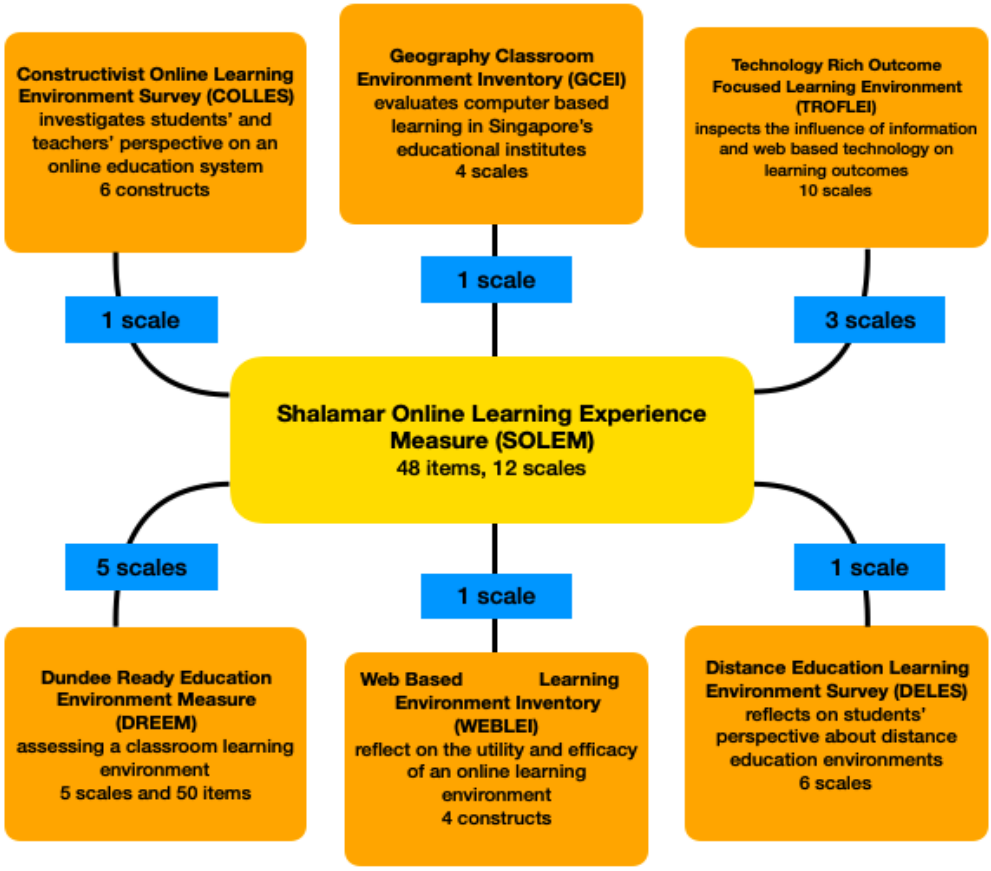
METHODS

a. Development of Shalamar Online Learning Experience Measure (SOLEM)

The development of SOLEM followed three key steps that are involved in learning environment scale development [5]. Extensive literature review was done to review previously available and validated instruments. First step was identification of individual scales and items. Total 56 items were selected and divided under 12 scales (See Appendix 1). These items were retrieved from 6 validated scales. The items were modified according to the perspective to fit to measure various dimensions of the online learning process. The item and scale selection were done by a panel of experts to enhance its capacity to measure the surgical learning process more comprehensively.

Briefly, various educational environment scales were explored and research materials were studied to identify vital elements of a high-quality online learning environment. First step involved reviewing previously validated learning environment instruments that could be modified for SOLEM. 12 scales were selected from six validated instruments. Second step was to categorize these scales based on Moos' three psychosocial dimensions. Third step was writing new items and adopting individual items for each scale. The initial version of SOLEM contained 56 items. Fourth step was expert validation.

Following scales were deemed appropriate for inclusion into SOLEM. Roff et al developed an instrument called Dundee Ready Education Environment Measure (DREEM) aimed to assess a classroom learning environment [6]. This instrument was based on 5 scales and 50 items. Aldridge et al created the Technology Rich Outcome Focused Learning Environment (TROFLEI) using the What Is Happening In The Class (WIHIC) scales [7]. This instrument is based on 10 scales and it inspects the influence of information and web-based technology on learning outcomes. Chang et al devised an instrument named Web Based Learning Environment Inventory (WEBLEI) that served to reflect on the utility and efficacy of an online learning environment, this questionnaire consists of four constructs [8]. Walker has created Distance Education Learning Environment Survey (DELES) to reflect on students' perspective about distance education environments, the survey is based on six scales [9]. Constructivist Online Learning Environment Survey (COLLES) was developed by Taylor et al to investigate students' and teachers' perspective on an online education system, this survey was based on six constructs [10]. Teh et al developed Geography Classroom Environment Inventory (GCEI) based on four scales to evaluate computer-based learning in Singapore's educational institutes [11]. For the purpose of our measure, 5 scales were



Development of the SOLEM

adapted from DREEM, 3 scales from TROFLEI, 1 scale from WEBLEI, 1 scale from DELES, 1 from COLLES, 1 scale from GCEI.

Most of these instruments were based on Moos' psychosocial dimensions of a learning environment, which were developed in order to measure the perceptions of learners. Moos conceptualized that a well-planned psychosocial environment should cover three dimensions: relationship dimension, personal growth dimension and system maintenance, and change dimension.

b. Expert Validation of SOLEM

In order to improve the construct validity of SOLEM, a questionnaire was prepared which was reviewed by an eight-member expert panel involved in online education and research related to the online learning environment. Word document consisting of scale items, operational definitions and instructions on reviewing the items was sent to experts. After expert validation questionnaire was revised and three items were deleted.

c. Pilot testing and performing Exploratory Factor Analysis:

The SOLEM questionnaire was administered to undergraduate medical students enrolled in Shalamar Medical and Dental College during online classes for pilot testing. Questionnaire was disseminated through Google Forms as it is a more reliable and time efficient method compared to the traditional paper-based version. The sample of students was drawn from medical undergraduate students of Shalamar Medical and Dental college. 162 Students responded to items using a five-point Likert scale (strongly agree, agree, neutral, disagree, strongly disagree). All the data from participants was inputted to SPSS v.20 and analyzed to measure the construct validity and reliability.

There were three distinct components of the analysis in the current study. Initially the mean, standard deviation and Cronbach's alpha coefficient were computed for each of the 12 scales in SOLEM. The second component of analysis consisted of exploratory factor analysis (EFA). Principal component analysis of the final SOLEM suggested that this questionnaire is structurally sound. The final version of the SOLEM questionnaire consists of 48 items assigned to 12 underlying scales. Table 1 contains the name of each scale included in SOLEM along with sample items.

RESULTS

The newly designed instrument, SOLEM, was subjected to expert validation to assess the relevance, face validity and content validity. Table 1 shows the I-CVI of each item. Three weak items were excluded.

Table 1: I-CVI and Factor Loading of each item in SOLEM

Theme	Representative Items	I-CVI	Factor loading
Perception of learning /teaching	1.The learning process was well planned, well organized and structured	0.99	0.657
	2.The assessment was well aligned to the content taught	0.98	0.619
	3.The learning process was focused	0.97	0.628
	4.The learning process was conformed to learning objectives	0.88	0.706
	5.The teaching/learning was student centered	0.93	0.538
	6.The teaching was too teacher centered	0.82	0.610
	7.The learning process was simulating and engaging	0.95	0.581
Perception of teacher	1.The teacher was/were knowledgeable and trained	0.86	o.788
	2.The teacher helped to develop my practical skills	0.90	0.508
	3.The teacher was/were well prepared for his/her classes	0.87	0.808
	4.The teacher was/were committed to my learning	0.92	0.788
	5.The teacher gave clear examples to explain	0.78	0.766
Academic self-perception	1.I feel I am being well prepared for my career	0.82	0.707
	2.My problem-solving skills are being well developed here	0.81	0.716
	3 Learning strategies which worked for me before continue to work for me now	0.86	0.638
	4.I am confident about passing this year	0.79	0.584
Social self-perception	1.I felt too tired to enjoy this course	0.88	0.748
	2.I was rarely bored on this online learning system	0.91	0.638
	3.There is a good support system for students who get stressed	0.84	0.691
	4.I communicate regularly with other students in the course	0.93	0.634
Perception of atmos-phere	1.The atmosphere motivated me as a learner	0.90	0.760
	2.The learning activity was well organized and time tabled	0.96	0.692
	3. There were opportunities for me to develop my interpersonal skills	0.93	0.799
	4.I found the learning experience disappointing	0.89	0.670
	5.I was able to ask questions freely	0.97	0.677
Computer usage	1.There was effective support system to troubleshoot computer/technology related issues	0.98	0.629
	2.I was initially trained and was confident/competent using a computer/learning platform	0.91	0.565
	3.I was confident in using the world wide web to search information	0.96	0.622
Active learning	1.The feedback I receive from activities /quizzes was meaningful	0.99	0.623
	2.The activities /quizzes provided in the course enhanced my learning	0.86	0.602
	3.I felt motivated by the responses I got from activities /quizzes included in the learning activity	0.98	0.561
Teacher support	1.The teacher responded timely to my queries	0.93	0.743
	2.The teacher participated regularly in group discussions	0.94	0.751
	3.The teacher provided regular and constructive feedback on my learning progress	0.86	0.644
Design and appeal	1.The choice of colors and style used in the web text was clear and appropriate	0.83	0.712
	2.The material used in lectures shows originality and creativity in the layout	0.89	0.673
	3.I found the graphics used in software were well designed and visually appealing	0.93	0.655
Order and organization	1.The learning objectives were clearly stated for each topic	0.95	0.723
	2.The information presented in the course was well recognized and easy to follow	0.95	0.745
	3.The information presented was appropriate and related to the topic studied	0.86	0.759
	4.I was able to easily find help on terms or concepts I did not understand	0.82	0.655
	5.The link provided in the topic were clearly visible and were relevant and appropri-ate to the topic being studied	0.87	0.712
Resource adequacy	1.The instructions provided to use the tools within the online platform were clear and precise	0.78	0.677
	2.The software I used was suitable for participating fully in the course	0.84	0.564
	3.The software applications needed to participate in this course were provided	0.86	0.642
Reflective thinking	1.I felt a sense of satisfaction and achievement about this learning environment	0.92	0.736
	2.I found using the Internet for learning was simulating	0.84	0.637
	3.I felt the web-based learning approach can substitute for or enhance the normal classroom approach	0.76	0.683

The second step involved factor analysis to assess the reliability of the scale items, construct validity in terms of estimation of Cronbach's alpha values and factor loadings. The aim of factor analysis is to identify and explain the co-relationship between variables which forms the basis of learning environment research validation through principal component analysis (PCA), a technique to reduce the dimensionality of each dataset, and to identify new uncorrelated variables in order to maximize the variance [12]. In PCA different method of rotations are applied to enhance and simplify the interpretability. In orthogonal rotation, the factor axes are kept at right angle to each other while in non-orthogonal (oblique) rotation methods, the factor axes are not at right angle to each other, the most popular method appears to be the varimax rotation [12]. Apart from the selection of most relevant analytic rotation methods, researchers need to clarify factor loading of individual items and scale to construct a validated learning environment survey. The value of factor loading is variable in literature and has a major role to play in exploratory factor analysis. Some studies consider factor loadings of 0.30 and 0.35 acceptable whereas other studies labelled factor loadings of 0.40 for an item on their a priori scale acceptable [12]. Standardized factor loading should range from 0.5-0.7 [13]. Such high factor loading indicates that items are strongly connected with associated constructs.

We established the construct validity using content validity and principal component analysis (PCA) PCA yielded 7 factors for the SOLEM. The 7-factor solution accounted for 72.6% of variance, while 27.4% of the overall variance remained unaccounted. 48 items had factor loading greater than 0.5, items with factor loadings below 0.5 were removed from SOLEM. Content validity was verified through previous research and expert's interaction in the area of online learning. Content validity index and factor loading of items are detailed in Table 1.

In order to measure internal reliability of the questionnaire, Cronbach's alpha coefficient was calculated. The Cronbach alpha for the questionnaire and subscales were high and suggested that SOLEM has high internal consistency. The Cronbach alpha scores for the questionnaire are detailed in Table 2.

DISCUSSION

The history of research of learning environments dates to the 1950s. However, these scales did not depend on a sound and clear hypothesis. For classroom environment instruments, it is important that these dimensions provide coverage of Moo's three general categories of human environment [14]. In the 1960s, Walberg built a learning environment instrument called the Learning Environment Inventory (LEI). Later, Fraser and Wubbels created a Classroom Environment scale stemming from Moo's psychosocial climate dimensions [15]. The work of Walberg, Fraser and Moo has catalyzed the research related to the development and application of learning environment scales. Although physical class room environments are different from the online class rooms, the principles of teaching and learning remain the same.

In the course of the last two decades, the advent of digital innovation and E-learning has fundamentally changed the structure of training and learning conditions. Albeit web-based learning in clinical training is a fairly unpretentious idea, in any case this pandemic has roused us to investigate alternate methods of achieving set academic standards of medical education. Learning environment is defined contrastingly by different individuals, for the purpose of this study, a learning environment alludes to diverse physical locations, contexts and cultures in which mentors and students interact to take part in learning activities.

Online instruction is a formal educational process in which the instruction occurs when the learner and the instructor are not in the same place and internet technology is used to provide communication between the instructor(s) and student(s). To Siragusa (2005) online learning is when students are using the internet to interact with content, other students and their tutors. This range of definitions and interpretations of online learning is a reflection of the variety of ways educationalists, at all levels, use connected computers in learning.

Internet technology has influenced every function of educational institutes, from teaching, learning, monitoring student progress, to administration. Organizations have put expanding measures of assets into improvement of computerized functions both in foundation and course content. As per a survey directed by the Sloan Consortium in 2004, the number of students enrolled in online courses has exceeded 1.6 million in the USA [16]. It has become obvious that instructors need to establish new policies to manage web-based methods of educating and learning [17].

An internet education requires a healthy mix of instruction, collaboration, support, socialization and a stretched-out effort to make a compelling learning framework [18]. Interestingly, research to explore both the psychosocial and physical aspect of a networked classroom revealed that the classroom psychosocial environment (especially autonomy/independence and task orientation) was altogether and significantly connected with the learner's fulfillment with their learning [19]. However, different barriers were also identified that hinder online learning i.e. technical skills and technical barriers, learner motivation, social interaction and academic skills [20].

Table 2: Reliability for SOLEM

Scale	No of items	Cronbach's alpha
Perception of learning/teaching	7	0.868

Perception of teacher	5	0.912
Academic self-perception	4	0.887
Social self-perception	4	0.847
Perception of atmosphere	5	0.860
Computer usage	3	0.809
Active learning	3	0.889
Teacher support	3	0.879
Design and appeal	3	0.872
Order and organization	5	0.906
Resource adequacy	3	0.776
Reflective thinking	3	0.893

Exponential growth in the online education delivery medium has led researchers to probe about its quality and efficiency. Previous research highlights that learners are satisfied with the content quality and online learning experience [21]. Although, virtual classrooms seemed to deliver good learning outcomes and a degree of satisfaction among learners, yet results were not much improved upon than in the traditional classroom environment [22].

Moore (1989) explained three characteristic features of an online learning environment. These are, Student to course interaction, Student to instructor interaction and Student to student interaction. Haynes (2004) worked out the fourth component of a learning environment i.e student interface interaction. A well designed, focused and simple to explore course which unmistakably achieves the goals of an online learning environment shows the significance of student to course interaction [23] [24]. The importance of teacher support, aptitude, competence and feedback during online interaction has also been upheld [24]. The focus on the quality of content and technological adequacy enhances learning achievements.

Utilizing online learning environment instruments intended to gauge the effect of internet technology on students, we can start to quantify effectiveness of online education on knowledge and student's outcome dimensions. As tutors, education practitioners and learning environment analysts perform a significant role, they need substantial instruments to survey contemporary learning environments in order to develop an optimal learning environment. Unfortunately, research related to the efficacy of online education has not kept pace with the rapid growth of this system. Current research was done to develop and validate an instrument to investigate the quality of an online learning environment from a learner's perspective.

LIMITATIONS

The present study has a few limitations. The sample size was relatively small and participants were recruited from a single institute. Further research in this area with large and diversified samples should be conducted to enhance and validate the SOLEM questionnaire.

CONCLUSION

Due to the increasing prevalence of online education, it is of paramount importance for the E-learning service providers to investigate the productiveness of this system and to make effective strategies accordingly. The present study is suggestive in that it involved development and validation of a scale that provides feedback responses based on students' perception of the online learning environment. Using a sample of undergraduate medical students, this article has provided substantial validation of the SOLEM questionnaire and could be used to base and assess the quality of an online learning environment. Our study developed an instrument based on 12 scales, measures the perception of learners about the educational quality, tutors' competence, learning atmosphere and web-based services/resources in an economic and reliable way. The SOLEM can be used to explore methods in which teachers can make an online educational environment more conducive for students learning, thereby enhancing student outcomes. In short, SOLEM can function as an important tool for quality assurance of online learning process.

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Appendix 1

Shalamar Online Learning Experience Measure (SOLEM)™

Name:	**Age/ Sex:**
Year of Education:	**Institution:**
Date:	

			Strongly agree	Agree	Neutral	Partially agree	Strongly disagree	I-CVI
Perception of Teaching Learning Process	1	"The learning process was well-planned, well-organized and structured".	○	○	○	○	○	0.99
	2	"The learning process was focused "	○	○	○	○	○	0.97
	3	"The learning process was conformed to learning objectives"	○	○	○	○	○	0.88
	4	"I was welcomed and encouraged to participate in learning process"	○	○	○	○	○	0.92
	5	"The learning process was stimulating and engaging"	○	○	○	○	○	0.95
	6	"The teaching/learning was student-centered"	○	○	○	○	○	0.93
	7	"The teaching was too teacher-centered"	○	○	○	○	○	0.82
	8	"The assessment was well aligned to content taught"	○	○	○	○	○	0.98
Order and Organization	9	"The learning objectives were clearly stated for each topic"	○	○	○	○	○	0.95
	10	"The information presented in the course was well organized and easy to follow"	○	○	○	○	○	0.95
	11	"The information presented was appropriate and related to the topic studied"	○	○	○	○	○	0.86
	12	"I was able to easily find help in understanding of concepts that I do not understand"	○	○	○	○	○	0.82
	13	"The link/s provided in the topic were clearly visible and were relevant and appropriate to the topic being studied"	○	○	○	○	○	0.87

Perception of Teacher/ Educator	14	"The teacher/s was/were committed to my learning"	○	○	○	○	○	0.92
	15	"The teacher/s was/were knowledgeable and trained"	○	○	○	○	○	0.86
	16	"The teacher/s helped to develop my practical skills"	○	○	○	○	○	0.9
	17	"The teacher/s was/were well prepared for his/her classes"	○	○	○	○	○	0.87
	18	"The teacher/s gave clear examples to explain"	○	○	○	○	○	0.78
Teacher Support	19	"The teacher/s responded timely to my queries"	○	○	○	○	○	0.93
	20	"The teacher participated regularly in group discussions"	○	○	○	○	○	0.94
	21	"The teacher/s provided regular and constructive feedback on my learning progress"	○	○	○	○	○	0.86
Resource Adequacy	22	"The instructions provided to use the tools within online platform were clear and precise"	○	○	○	○	○	0.78
	23	"The software platform I used was suitable for participating fully in the learning activity"	○	○	○	○	○	0.84
	24	"The software applications needed to participate in this course were provided"	○	○	○	○	○	0.86
	25	"There was a little delay in opening and using the software applications used in this course"	○	○	○	○	○	0.76
Design & Appeal	26	"The choice of colors and style used in the web-text was clear and appropriate"	○	○	○	○	○	0.83
	27	"The material used in lectures showed originality and creativity in the layout"	○	○	○	○	○	0.89
	28	"I found the graphics used in learning platform were well-designed and visually appealing"	○	○	○	○	○	0.93
Computer / Technology Usage	29	"There was effective support system to troubleshoot computer/technology-related issues"	○	○	○	○	○	0.98
	30	"I was initially trained and was confident / competent using a computer/learning platform"	○	○	○	○	○	0.91
	31	"I was confident in using the world wide web to search information"	○	○	○	○	○	0.96
	32	"I was able to reconnect to the network if anything went wrong"	○	○	○	○	○	0.89

Active Learning	33	"The feedback I receive from activities/quizzes was meaningful"	○	○	○	○	○	0.99
	34	"The activities/quizzes provided in the course enhanced my learning"	○	○	○	○	○	0.86
	35	"I felt motivated by the responses I got from activities/quizzes included in this learning activity"	○	○	○	○	○	0.98
Perception of Atmosphere	36	"The learning activity was well-organized and time-tabled"	○	○	○	○	○	0.96
	37	"The atmosphere motivated me as a learner "	○	○	○	○	○	0.9
	38	"There were opportunities for me to develop my interpersonal skills"	○	○	○	○	○	0.93
	39	"The atmosphere was comfortable for online learning process"	○	○	○	○	○	0.83
	40	"I found the learning experience disappointing"	○	○	○	○	○	0.89
	41	"I was able to ask questions freely"	○	○	○	○	○	0.97
Academic Self Perception	42	"I feel I am being well prepared for my career"	○	○	○	○	○	0.82
	43	"Last year work has been a good preparation for this year's work"	○	○	○	○	○	0.83
	44	"My problem-solving skills are being well developed and are improving"	○	○	○	○	○	0.81
	45	"Learning strategies which worked for me before continue to work for me now"	○	○	○	○	○	0.86
	46	"I am confident about passing this year"	○	○	○	○	○	0.79
Social Self Perception	47	"I felt too tired to enjoy this course"	○	○	○	○	○	0.88
	48	"I was rarely bored on this online learning system"	○	○	○	○	○	0.91
	49	"There is a good support system for students who get stressed"	○	○	○	○	○	0.84
	50	"I communicated regularly with other students in this course"	○	○	○	○	○	0.93
	51	"I was able to share resources and information with other students"	○	○	○	○	○	0.85
	52	"I often asked other students for help in activities we are doing"	○	○	○	○	○	0.76
Reflective Thinking	53	"I felt a sense of satisfaction and achievement about this learning activity"	○	○	○	○	○	0.92
	54	"I found using internet for learning was stimulating "	○	○	○	○	○	0.84

	55	"I feel I was in control of my learning as I review the material provided"	○	○	○	○	○	0.79
	56	"I feel the web-based learning approach can substitute for or enhance the normal classroom approach"	○	○	○	○	○	0.76

*The highlighted items were excluded and Final version of scale included 48 Items as shown in Table 1.

Archives of Surgical Research | View Point

Violence Against Doctors: A Rising Menace

Fatima Aslam

IMPORTANCE Violence against medical professionals is reaching unprecedented height and even in world class, well equipped hospitals, doctors face verbal or physical abuse. In primary care, mostly patient and attendant are the perpetrator, and these violent events are more frequently seen in surgical wards. The roles of hospital administration, judiciary, media, and government is crucial in maintaining the sanctity of medical profession and doctors are equally responsible for perseverance of their dignity and continuing efforts to nurture themselves into ethically competent physicians. Community leaders can be a part of this movement because they play an important role in influencing the public opinion. Such activities should be highlighted on social media to raise awareness in public about how a slight misstep can be professionally and emotionally damaging for a doctor, who is a human being at the end of the day, and to err is only human.

KEY WORDS: Violence, Doctors, Harassment, Medical Profession, Ethics

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View Point

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"No physician, however conscientious or careful, can tell what day or hour he may not be the object of some undeserved attack, malicious accusation, blackmail or suit for damages..." [1]

The above paragraph of a renowned Journal of the United States, written 135 years ago should be a telltale and equally prophetic. In the past, doctors were highly revered and respected by patients and society at large. However, this is becoming extremely rare with the advancing times. The word violence has a ring of intentional hurt and to use it against medical professionals, who are acting according to medical ethics is unthinkable. Stress and violence are on a rise in health sector workplaces and doctors are high on the list of occupations with serious stress levels.

On daily basis, incidents occur in which physicians are being crushed, hurt, and verbally abused by common man, if a patient dies even when the doctors have done their utmost in saving their life. Although violence in the medical profession is common around the globe, countries like Pakistan are more susceptible, because of the already prevalent ethnic and political violence and a fragile law enforcement infrastructure [2]. The decline in literacy rate in Pakistan is directly contributing to lack of general knowledge about diseases, precautionary measures and their treatment leading to delayed diagnosis along with unrealistic expectations from a doctor to do some miracle. Also, the shortage of medical staff is another problem that Pakistan is facing in health sector, thus causing frustration in both the consumer and producer due to increase workload on doctors and unbalanced patient to doctor ratio.

Violence against medical professionals is reaching unprecedented height and even in world class, well equipped hospitals, doctors face verbal or physical abuse. In primary care, mostly patient and attendant are the perpetrator, and these violent events are more frequently seen in surgical wards. Some of the countries, other than Pakistan, where violence against doctors has been reported include the UK, USA, Germany, Australia, China, Turkey, Israel, Nepal, Myanmar, Saudi Arabia, and India [3-6].

The role of media in reporting the incidents of medical negligence is crucial. Media creates hype without any evidence in a given situation of the supposed negligence. Just like any other profession, black sheep also exist in media who create sensation to make money by broadcasting fake stories of medical errors. The statistics related to violence against doctors in Pakistan are immensely appalling while the events of public intolerance are highly disappointing. Electronic and social media presents doctors as looters and butchers thus defaming and ruining their reputation for the sake of making money with the famous notion "if it bleeds, it leads"; which applies not on the choice of events that media covers but the manner in which it is covered. They report false news and sensationalize a small slice of what happens and craft it into an entire story of their own.

In a local study conducted in 2018, of 74% physicians experiencing violence, almost 88% did not receive any help from hospital administration which is an alarming situation. Female doctors face violence usually in the form of sexual harassment and it becomes difficult for them to perform night duties due to ineffective security measures in hospitals[7]. The most disturbing fact was that Pakistan ranks

first in the list of countries documenting percentage of violence against doctors with 85% mild (verbal and emotional) abuse as compared to 44% in Australia.

The phenomenon of "YI NAO" means healthcare disturbance. Yi Nao gangs are groups of largely unemployed people with a designated leader. They threaten and assault hospital personnel, damage facilities and equipment and prevent the normal activities of hospital, usually to obtain compensation for actual or perceived medical malpractice[8,9].

REASONS OF VIOLENCE:

There is a long list for genesis of violence which includes patient's demise, disagreement over hospital bills, dissatisfaction with services, Yi Nao, prolonged treatment tenure, ill-trained doctors in communication skills, long working hours of doctors, ineffective paramedics in dealing with violent situations, quacks spoiling the patients and later near fatal cases ending in hospital emergencies [6,10].

ISSUES FACED BY GYNAECOLOGY DEPARTMENT:

Looking into different specialties of medical profession like gynaecology, surgery and family medicine, each one has a set of problems leading to violent acts against doctors. Owing to the population increase in Pakistan, the workload in gynaecology department is on a rise. One of the leading causes of violence in this field is female baby denial. Patient and their attendants have a wrong assumption of male baby and as soon as the mother delivers a female child, they blame the doctor for forged reports and replacement of the infant. Also, the frequency of theft of newborns from gynaecology wards have increased in last few years leading to patients' assaulting health professionals and damaging hospital property. On the contrary, when being asked for blood donations for their dying patients due to ruptured uterus, the very same attendants usually refuse and vanish away.

PERSPECTIVE OF SURGEONS & FAMILY PHYSICIANS:

Informed consent has a vital role when dealing with patients, especially in surgical wards. Lack of communication between doctors, patients and paramedics lead to dissatisfaction and creates a vacuum resulting in outburst by society in an intolerant way. Family physicians usually face the brunt of their patient when he/she visits multiple doctors and each one of them blames the former doctor for wrong prescription and faulty diagnosis.

ADMINISTRATIVE ISSUES IN HOSPITALS:

When talking about administrative issues regarding violence in hospitals, three main factors are inter-related and directly contribute to violence. They are shortage of healthcare professionals, increase in growth rate and declining literacy rate. As per WHO standard of 1:1000 of doctor to population, there should be 110,000 doctors in Punjab [11]. Thus, there is currently shortfall of 37,174 doctors in Punjab province only. Insecure health professionals are leaving the country for a better future abroad contributing to brain drain in Pakistan.

There are **three challenges** that need to be addressed by hospital administration so that mishaps can be avoided. They include:

1. Crowd management in hospitals since there is lack of adequate waiting areas for visitors and inefficient queue management system leading to frequent quarrels between patients.
2. Non-compliance to various medical acts, rules, processes
3. Inadequate infrastructure and security system

These challenges can be dealt by:

1. Improving hospital infrastructure with particular reference to entry and exit as well as controlled entrance for hospital emergency, authorized staff, patients, and visitors.
2. Professionally designed fool proof security system should be put in place with major emphasis on surveillance, ongoing capacity building of security staff.
3. A toll-free number for complaints should be provided to patients and online registration of complaints should be set up.
4. A special task force should be created for addressing hospital violence issues with development of standard operating procedures and violence reporting mechanisms.
5. For the satisfaction of patient and their families, dedicated counseling rooms should be made where they are well informed about their illness.

LEGAL OPINION:

Sensitivity of medical profession is higher as compared to other professions since doctors are dealing with human lives directly and this is one of the main reasons, that issues related to their negligence get highlighted in no time. There are laws for protection of doctors but unfortunately there is no implementation of them, and since doctors do not take interest in legislation processes being initiated by healthcare commission, they end up making themselves more vulnerable to acts of violence. A doctor protection act was developed in India in 2010 but it could not be implemented in its true spirit which shows that fear of law may be a deterrent in various crimes but does not hold true in healthcare [12]. Role of healthcare commission is crucial in protecting the rights of doctors and penalizing if found guilty after thorough probing of the complaints launched against them. Punjab government has passed an occupational safety and health act in January 2019, but its implementation is still a challenge [13].

RESPONSIBILITY OF MEDIA:

Electronic and social media has a strong impact in shaping the public opinion for doctors. Usually judgmental and inaccurate reporting of medical negligence shake peoples' faith in doctors. It is the responsibility of healthcare professionals to run awareness raising campaigns on social media, TV, and radio to change the perception of general public regarding respect and protection of doctors. Also, continuous advocacy with law makers and policy makers is need of the day to end the violence against holistic practitioners. The leadership of medical community should reform the present-day curriculum with emphasis on communication skills, awareness of legal rights and knowledge of media personnel in hospitals.

WAY FORWARD:

The roles of hospital administration, judiciary, media, and government is crucial in maintaining the sanctity of medical profession and doctors are equally responsible for perseverance of their dignity and continuing efforts to nurture themselves into ethically competent physicians. Community leaders can be a part of this movement because they play an important role in influencing the public opinion. Such activities should be highlighted on social media to raise awareness in public about how a slight misstep can be professionally and emotionally damaging for a doctor, who is a human being at the end of the day, and to err is only human.

RECOMMENDATIONS:

1. Doctors workload should be reduced.
2. Communication skills, ethics and professionalism should be essential component of medical teaching.
3. Positive role modeling and leadership by seniors can help the junior doctors in becoming holistic practitioners.
4. Learning skills to deal with critical situations should be developed.
5. Laws should be placed to decide extent of media coverage of doctors
6. Provision of healthcare services appropriate to the need of patients should be ensured.
7. Doctor to patient ratio should be adjusted appropriately.
8. Well-equipped primary and secondary healthcare facilities to ensure provision of tertiary healthcare facilities to patients.
9. Role of print, electronic and social media in defamation of doctors is particularly important.
10. Implementation of laws for punishment of complainant in case of wrong complaint.
11. Doctors should avoid criticism of previous treatment by fellow colleagues i.e., AVOID BLAME GAME
12. Doctors are underpaid and over-worked so their salary structures should be revised.
13. Police check posts should be established inside each hospital as an insecure doctor cannot work to his full potential.
14. Development of counseling skills center in each hospital
15. Training of nurses and paramedical staff to communicate politely and effectively with the patients.
16. Unity of doctors should be emphasized repeatedly.

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Archives of Surgical Research | Case Report

Solid Ameloblastoma: A Case Report

Ahmad Liaquat, Moghees Ahmad Baig, Ayaz Mehmood, Tooba Saeed

IMPORTANCE Ameloblastoma is a very uncommon neoplasm of odontogenic origin, which is a benign but locally aggressive tumor. It causes the expansion of the jaws' cortices with gross disfigurement and impairment in esthetics and functions. Here we present a 42 years old lady who presented to us with large solid ameloblastoma of the left side of the mandibular body and ramus. Left segmental resection with disarticulation of condyle and 1cm linear safe margins of mandibular body region was done. Stereolithic model was used to shape the reconstruction plate preoperatively and applied at the defect site to maintain the continuity of the mandible.

KEYWORDS Ameloblastoma, stereolithographic model surgery, mandibular tumor

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Case Report

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Ameloblastoma is a very uncommon true neoplasm constituting only 1 % of all jaws' cysts and tumors. It is benign and has an odontogenic origin.[1] Ameloblastomas have a notorious reputation for their locally invasive and highly aggressive characteristic[1], causing expansion of the jaws' cortices with infiltration into soft tissue. Most of the ameloblastomas are found in the age group ranging from third to the fourth decade, with an average age of 38.9 years. It has an equal incidence rate in both genders, frequently reported in the mandible, particularly the molar ramus region.[2] In the mandible, the most common site is the molar and ascending ramus region accounting for 39%, and 16% occurred in the molar premolar region and 9% in the anterior region.[3] It has a very high recurrence rate, which is supported by the literature. [1] It has a rare tendency to transform into full-blown malignancy with metastasis.[4] Radiographically, these tumors mostly present a multilocular radiolucency and less frequently as unilocular radiolucency. When presented as multilocular radiolucency, they have a distinct soap bubble pattern; division of the bony spaces with the trabeculae. [3] They present as well-circumscribed slow-growing radiolucencies.[3] Ameloblastomas tend to associate with unerupted teeth, but that is not always the case. The status of teeth associated with ameloblastoma is vitally viable, but they may have mobility, and in some cases, there may be resorption of the roots of associated teeth.[3] Ameloblastomas have a diverse histological and clinical pattern.[5]

CASE REPORT

A 42 years female presented to the outpatient department (OPD) of oral and maxillofacial surgery, with the chief complaint of swelling over the left mandible for last two years. Extra oral examination revealed marked facial asymmetry due to a large mass, measuring approximately 9x5cm on the mandible's left side—Posterio-anteriorly, extending from the left angle of the mandible to the left corner of the mouth. Superio-inferiorly the swelling was extending from the left malar region to the hyoid bone region on the neck. The mass was well-demarcated, firm to hard in consistency with well-defined borders. The overlying skin colour, texture, and temperature were normal. All cranial nerves were intact especially facial and trigeminal nerves. There was no clinical evidence of cervical lymphadenopathy.

On intraoral evaluation, there was a buccal cortical plate expansion. The occlusion was intact. No discharge or ulceration was noted. Oral hygiene was poor, with heavy calculus and plaque deposits. Dentition on the left side of the mandible was sound except for the first molar broken down roots, which had no infection sign. Initially, an OPG was done, which revealed a large multilocular radiolucency with well-circumscribed borders extending from the alveolar ridge level to the inferior border of mandible over the mandible angle region, anteroposteriorly the lesion was extending from the left second molar to ascending ramus region, pushing the roots of the second molar mesially. Moreover, the boundaries of the inferior alveolar canal were also not appreciable. A CBCT scan with 3D reconstruction revealed a multilocular radiolucency on the left side of the mandible with the expansion and erosions of both buccal and lingual cortices.

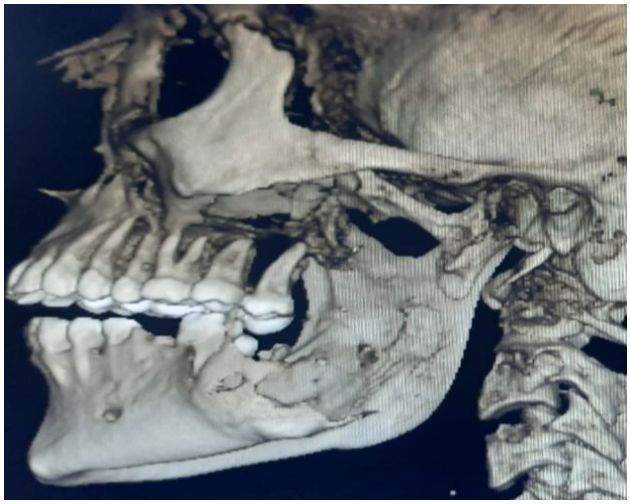

Figure 1 CBCT showing the destruction of the buccal cortex of the mandible.

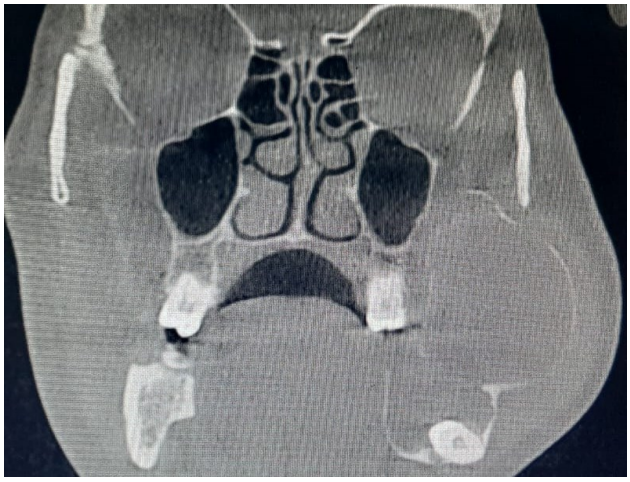

Figure 2 Coronal view showing large multicystic lesion of the mandible.

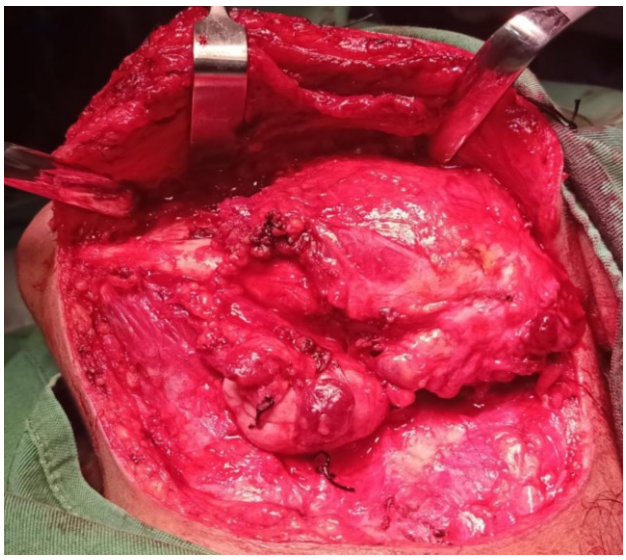

Figure 3 Per-Operative exposed tumor

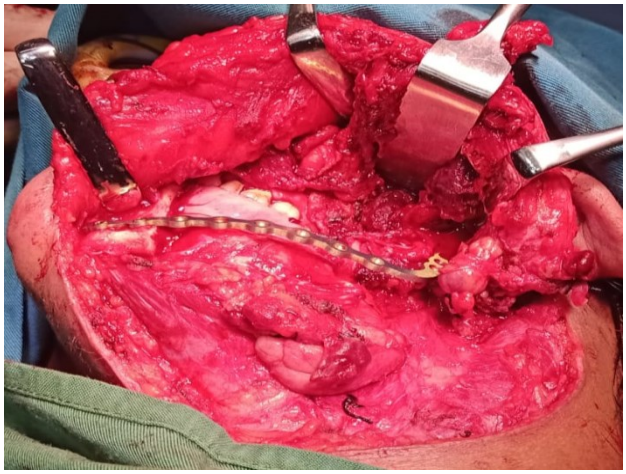

Figure 4 Reconstruction plate placed after tumor resection

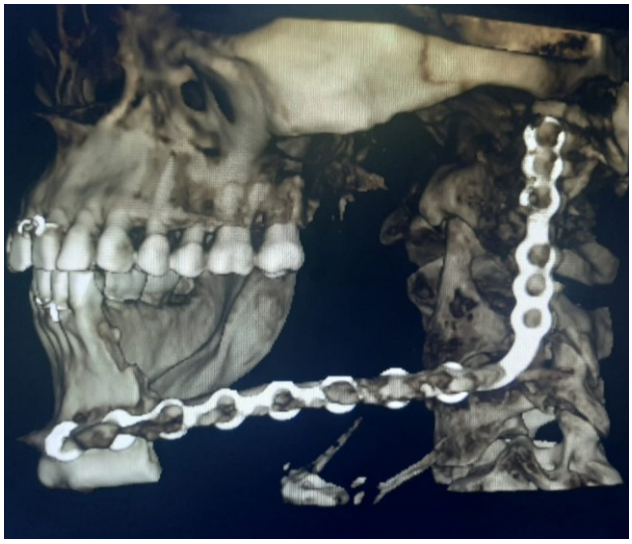

Figure 5 Postoperative CBCT scan

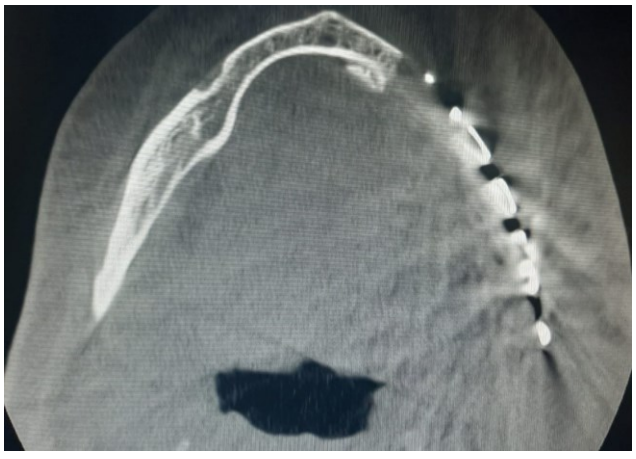

Figure 6 axial view showing the symmetry of the reconstruction plate

As per the radiographic findings, the differential diagnosis included: Multicystic Ameloblastoma, Odontogenic

Keratocyst, Odontogenic myxoma, and Central giant cell granuloma. Under local anesthesia, an incisional biopsy was carried to confirm the diagnosis; solid ameloblastoma was confirmed on initial histopathological evaluation.

A treatment plan of tumor resection with 1cm linear safe margins and reconstruction with a recon plate and locking screws was carried out under general anesthesia.

Preoperatively, a stereo-lithic model was constructed, and model surgery was done on that. Mirror imaging of the right side of the mandible was done to shape the reconstruction plate according to the mandible's symmetry, to save the time in operating room. Postoperative recovery of the patient was uneventful. The surgical drain was removed after 24 hours. The patient was discharged on the third postoperative day. Follow up was done after 1 and 3 weeks and then in the third month. The facial nerve was intact, and there was no postoperative complaint. Follow up will continue for about 7 to 10 years to observe any recurrence.

Discussion

Ameloblastomas are classified into two main divisions, i.e., extraosseous, also known as peripheral or intraosseous, also known as central ameloblastoma. Peripheral ameloblastoma, as the name implies, is a slow-growing mass that is mainly confined to gingiva or alveolar mucosa without involving the underlying bony tissue. They are either sessile or pedunculated.[5] Intraosseous ameloblastomas of the jaws are further classified into unicystic, mixed cystic and multicystic, known as the solid variant.[6] Solid forms and the mixed cystic form of ameloblastomas have a very aggressive behavior and are notorious for their ability to recur.[5] The histopathologic variant includes the acnathmatous, follicular, and plexiform types and granular cell types.[9] Uncommon variants of ameloblastoma include keratoameloblastoma, clear cell, basal cell ameloblastoma, desmoplastic and proliferous ameloblastoma.[7] Among all these variants, the plexiform pattern is less aggressive with low recurrence.[8] Even though ameloblastoma has a very aggressive clinical course, they often present asymptomatic lesions which have a tendency to grow slowly, and there may be minimal swelling. Patients can present with symptoms such as dental malocclusion in the early stages. As the tumor grows, the patient has symptoms such as paresthesia of the affected region, pain and swelling. [10] The uniqueness of ameloblastoma is that it forms pseudopods into the marrow spaces of jaws with resorption of the trabecular bone, due to which the tumor margins are difficult to identify on pre-op and Intra –op radiographs. This is a significant reason for the recurrence of the tumor after surgical removal of the tumor. [12] Radiographically tumors may appear as being separated into portions, which represents differential resorption of the cortical plate and not actual separation of the tumor into different portions.[13] Recurrence of ameloblastoma presents after many years or even decades, owing to its tendency to grow very slowly after the primary surgery. [12] In the case of inadequate surgical removal of the primary tumor, the potential of the tumor into malignant transform increases. [11] Frequently on radiographic evaluation, ameloblastoma would have a characteristic appearance but not diagnostic radiographic appearance. [11] The neoplasm mostly appears as a unilocular radiolucency or a multilocular radiolucency with a typical honeycomb pattern because of trabecular bone presence. [11] Roots of the adjacent tooth or teeth may show resorption.[3] This tumor tends to be associated with an unerupted tooth, mostly mandibular third molar.[14] Treatment options for ameloblastoma of the mandible are controversial. Treatment can change according to its anatomic location and its clinical behavior. Treatment mostly consists of wide surgical resection, accompanied by enucleation and curettage. [12,15] Ameloblastoma has a high rate of recurrence. It can recur in 15 to 25% for resection cases, and in conservative treatment, its recurrence ranges from 75 to 90%. [15] Philipsen HP, Reichart PA, and associates in their research work mentioned that the recurrence rate was 17.7% for en-bloc resection and almost doubled for conservative therapy, i.e., 34.7%. [4]

Conclusion

Solid ameloblastoma is a benign but locally aggressive tumor of jaws that needs surgical resection. There is controversy in treatment methods of ameloblastoma. Conservative treatment has a higher recurrence rate as compared to surgical resection. Reconstruction plate adaptation on stereo-lithic model before surgery saves time in the operation room and has good esthetic results postoperatively

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Archives of Surgical Research | Case Report

Management of Acute Idiopathic Epistaxis During General Anesthesia

Aamir Bashir[1], Muhammad Naveed Azhar[1]

ABSTRACT: Spontaneous epistaxis during general anesthesia is a rare emergency. It is a potentially life-threatening situation which can compromise airway, breathing & circulation. Usually, mild epistaxis can occur during nasal manipulation and usually resolve spontaneously this external nasal compression. In this case, there was no obvious cause of epistaxis and it didn't respond to external nasal compression and xylometazoline. We are presenting a case of 27 years' old who developed Idiopathic Spontaneous Epistaxis which failed to resolve with conventional measures and required intervention by maxillofacial surgery team at a tertiary care cancer center in Lahore, Pakistan.

KEYWORDS Idiopathic epistaxis, general anesthesia, management

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Case Report

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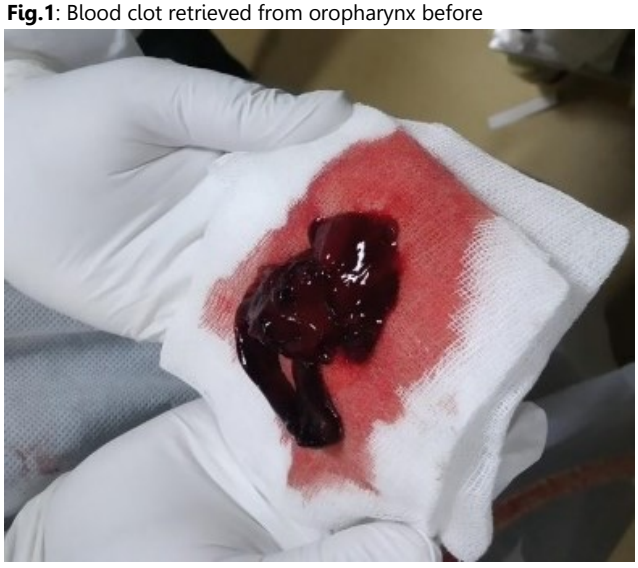
Epistaxis can occur during general anesthesia due to multiple reasons like iatrogenic nasal trauma with NGT & ETT, nasal tumors, coagulopathy, foreign body or vascular lesion. Epistaxis can be divided into anterior & posterior on the basis of anatomical origin, with the majority being classified as 'anterior', arising from an anastomotic network of vessels in the nasal septum known as Little's Area. The majority of these bleeds are self-limiting or settle with xylometazoline and external nasal compression.

CASE REPORT

A 27 years old male patient without any significant past medical history presented for cystoscopy & transurethral resection for carcinoma of urinary bladder. General anesthesia was induced with intravenous medication followed by insertion of I-Gel # 4 and maintenance on sevoflurane, oxygen & air. After few minutes, his SpO2 dropped and there was difficulty on manual bag ventilation. There was small amount of blood coming out from the nostrils. FiO2 turned to 100% and planned for endotracheal intubation. After getting EtO2 > 90%, Suxamethonium was given & I-Gel was removed. There was a big clot of blood in oropharynx which was removed with Magill forcep (Fig.1), suction was done with Yankauer and immediately intubated with cuffed ETT # 7.5mm. Before starting IPPV, ETT was suctioned with nelton drain, which was dry, then patient was put on IPPV. ETT confirmed with capnoghraphy, bilateral chest rise and auscultation of four quadrants of chest. After securing the airway, Xylometazoline 0.05% spray was instilled in each nostril followed by external nasal compression for 5 minutes. After removal of external nasal compression, oropharynx was examined with Laryngoscope, there was persistent blood coming out from nasopharynx. Throat pack was put in, external nasal compression was applied again and maxillofacial surgery team was called for their assessment. The maxillofacial surgery team performed nasal endoscopy but there was no obvious source of bleeding but laryngoscopy revealed fresh blood coming from nasopharynx. It was decided to do anterior and posterior nasal packing after which bleeding stopped. At the end of surgical procedure, patient was extubated fully awake. After monitoring in post anesthesia care unit for 2 hours, he was shifted to ward. There was no more bleeding from the mouth. Postoperative discussion with patient revealed he never had any epistaxis throughout his life. No coagulation abnormalities were identified from routine laboratory investigation. Nasal pack was removed after 24 hours and patient discharged to home.

Fig.1: Blood clot retrieved from oropharynx before



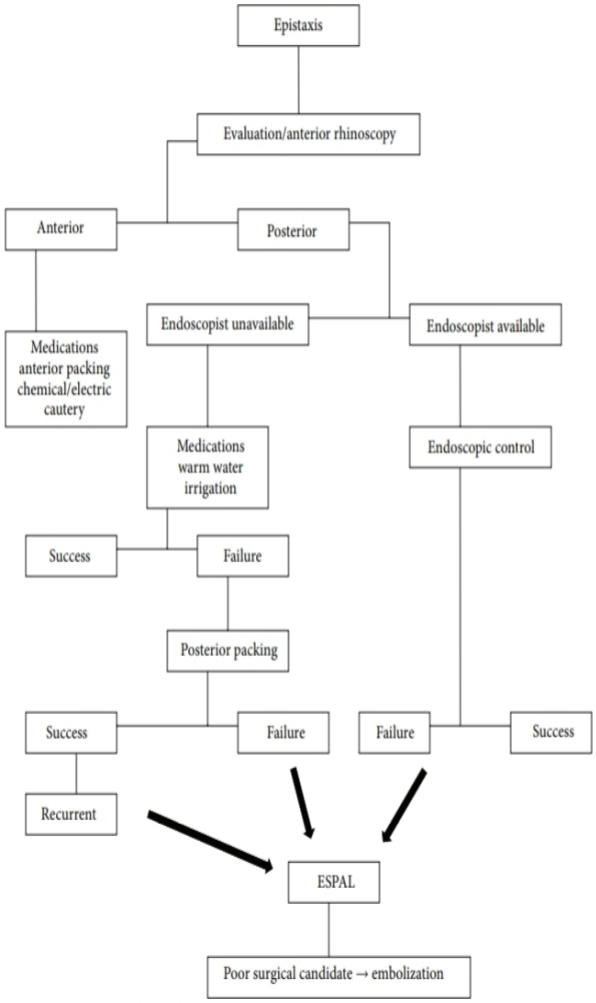


Fig. 2: Algorithm for management of epistaxis

DISCUSSION:

Intraoperative spontaneous epistaxis, although rare, may result in significant anesthetic complications, most important is airway compromise. The differential diagnosis includes; vascular lesion or tumor, nasal foreign body, nasopharyngeal angiofibroma, bleeding diathesis like haemophilia VIII, haemophilia IX and Von Willebrand Disease, & vascular disruption at the anterior nasal arteries Kiesselbach plexus etc. With an estimated 60% of the population believed to suffer an episode of epistaxis, the burden of this condition is significant. Despite this prevalence, only 10% of cases are believed to require medical input[1]. Of the cases that are brought to medical attention, the majority are anterior bleeds and few require surgical intervention[2].

Kiesselbach's plexus is comprised of multiple arteries that are the branches of internal carotid artery including: the anterior and posterior ethmoidal arteries, sphenopalatine artery, superior labial artery, and the greater palatine artery[3]. The most common cause is from the anterior nasal arteries from the dry nasal mucosa, nose picking, mucosal hyperemia and chronic excoriation.

During general anesthesia, it is rare to develop epistaxis without nasal manipulation and unknown coagulopathy. Various measures including external nasal pressure, nasal packing, use of Xylometazoline and phenylephrine has been used for its treatment[4,5]. Selected cases may require surgical interventions like Endoscopic ligation of the sphenopalatine artery (ESPAL)and various others modalities[6].

CONCLUSION:

We concluded that, epistaxis in anesthetized patient can lead to significant compromise of airway. It should be considered and managed promptly. Most of the cases usually settle with conservative measures, however, selected patients may require surgical interventions.

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The authors must comply with these important checklist items prior to submitting their manuscript for publication as the non-compliant manuscripts would be returned without review: -

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2. The submission file is in Open Office, Microsoft Word, or RTF document file format. The text is single-spaced; uses a 12-point font; employs italics, rather than underlining (except with URL addresses); and all illustrations, figures, and tables are placed within the text at the appropriate points, rather than at the end.
3. All original manuscripts should have Abstract in structured format up to 350 words. It should mention Objective, Methodology, Results, Conclusions and appropriate Key Words.
4. Please strictly follow the author guidelines for writing your manuscript. Non-compliant manuscripts would be returned without review without any exception. Referencing should be done through Mendeley, Endnote or any other such referencing software. In text citation should be in form superscript. The manuscripts with improper citation would be retuned without review. A sample manuscript submission file may be downloaded from this website.
5. The submission files should have a. Cover Letter describing the value of research work being submitted, b. Title Page containing the Manuscript Title, Authors, affiliations, contributions—an example of title page can be downloaded from this website, c. Article Text File having body of the main manuscript, d. Images and Tables, e. IRB approval Letter, f. Signed Letter of Undertaking, g. Consent Form for Case Report h. Article Processing Charges Submission Proof, i. Ethical Undertaking. Make sure that quality of Images is according to specifications provided in author guidelines. j. Reviewer Suggestion Form. k, Disclosure Form
6. Title page should contain title of the write-up, Name of the author/co-authors, their qualifications, designation & institutions they are affiliated with and mailing address for future correspondence, E-mail address, Phone, Cell Phone number besides a short running title of the manuscript. Don't type the name of the author/s on other pages in the manuscript except the title page to ensure the double blinding of the review process.
7. Prior to submission the manuscript should be checked for plagiarism preferably through Turnitin or some other medium and the similarity index should exceed 19%.
8. You have the proof in PDF/ JPEG form of submission of Article Processing Charges (APC).
9. All submissions are received through online portal through www.archivessr.com.
10. All randomized control trials should be prepared according to CONSORT Guidelines. All Clinical Trials submitted for publication must be registered in a registry e.g. https://clinicaltrials.gov/. Provide registration number.
11. Disclosure regarding source of funding and conflict of interest if any besides approval of the study from respective Ethics Committee/Institution Review Board.
12. Manuscript must be submitted along with IRB/Ethics Committee Approval letter.
13. Case Reports should be submitted along with Consent Form wherever applicable.

Corresponding Author Name_____ Sig. _____

Date _____

Manuscript Title: _____

_____

Further Considerations:

- Manuscript has been checked for correct spelling and grammar
- All Reporting Guidelines have been met
- All references mentioned in the Reference List are cited in the text, and vice versa
- All figures and tables are cited in text
- Permission for use of copyrighted material from other sources has been obtained
- A conflict of interest statement is provided, even if the authors have no conflicting interests to declare
- All research and clinical trials are registered in a public registry
- Journal policies detailed in this guide have been reviewed
- Referees and reviewers suggested by author(s) comply with journal policies as well.

3. BEFORE INITIATING SUBMISSION PROCEDURE

Ethical Confines

The work detailed in the manuscript must be approved by the appropriate ethical committees related to the institution(s) in which it was performed, including verification that all subjects involved gave informed consent. Records of written consent must be kept by the author. Studies involving experiments with animals must follow institution guidelines for the care of animal subjects. Any identification markers of patients and volunteers – including names, initials, and hospital numbers – must NOT be used.

Declaration of Interest

All authors must disclose financial and personal relationships with individuals or organizations that could potentially introduce bias to their article. Examples of possible conflicting interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications or registrations, and grants or other funding. If there are no interests to declare, then please: 'Declaration of interest: none'. This summary statement will be published if the article is accepted.

Submission Declaration and Verification

Verify that the work described has not been published previously (except in the form of an abstract, a published lecture or academic thesis), that it is not being considered for publication anywhere else, that its publication is approved by all authors, and by the responsible authorities/institutions where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form without the written consent of the copyright-holder. Verify that the work is original – all manuscripts are checked for plagiarism, and if found to be plagiarized above a certain degree, the author is liable to be blacklisted.

Use of Impartial and Inclusive Language

Inclusive language acknowledges diversity, conveys respect, is sensitive to differences, and promotes equality of opportunity. Content must not imply that one individual is superior to another on the basis of age, gender, race, ethnicity, culture, sexual orientation, disability or health condition. Authors should ensure that writing is free from bias, stereotypes, slang, and references to dominant culture. Avoid using markers of identification – including age, gender, race, ethnicity, culture, sexual orientation, disability or health when referring to subjects unless absolutely necessary. Always use the gender-neutral 'they' when referring to singular subjects unless the gender of the subject has particular influence on the research matter.

Authorship and Author Rights

Manuscripts by multiple authors must be signed by all the authors and contain details of contribution of every individual author. All authors must fulfill criteria for authorship. Authorship credit should be based on:

- Significant contribution to formation or design of study, procurement of data, or analysis and interpretation of data (Acquisition of funding, collection of data, or general supervision of the research group alone does not justify authorship)
- Drafting the article or revising it analytically
- Final approval of the version to be published
- Agreement to be responsible for all aspects of the work, and ensuring that the accuracy or integrity of any part of the work is maintained.

If a large, multi-center group has conducted the work, the group should identify the individuals who accept responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above and complete journal-specific author and conflict of interest disclosures. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Other members of the group should be listed in the acknowledgements. In case of suspicion of gift authorship the journal may refuse further processing of the manuscript. Manuscripts with more than *Eight* authors will not be accepted for further processing and will be rejected. An author (or employer or institution) has certain rights to reuse work that this journal will not infringe upon.

Registration of Research and Clinical Trials

All types of research studies and clinical trials involving human participants should be preferably registered prior to submission, and proof of registration must be provided. Unregistered trials and studies may not be published.

Role of Funding Source

The funding source must be disclosed along with their degree of involvement with the research matter, if any, in the design, collection, analysis or interpretation of data; in the writing of the article, or in the decision to submit the article for publication. If the funding source had no involvement, then this should be stated. Any authors found guilty of scientific misconduct will be blacklisted from future publications.

4. PREPARATION

Reviewing Process

This journal is reviewed using a *double blind* method through OJS. The following categories the journal will accept, out of guest editorials, original articles, review articles, case reports, clinical updates, short communications, book reviews, case studies, clinical notes, Continuation of Medical Education (CME), obituaries , letters, Knowledge-Attitude-Practice (KAP) studies, routine surveys and cross sectional studies. The authors are required to suggest potential refrees for the review process. The journal however would have to discretion to get the article reviewed by the suggested faculty or not.

Reporting Guidelines

Compliance with the relevant reporting guideline is mandatory for submission of the following guidelines:

1. Submit a completed checklist, indicating the page numbers where compliance to the guidelines was ensured.
2. Mention in the 'Methods' section that the research is being reported in line with the relevant guideline, which should be named and cited.

Randomized Controlled Trials

All randomized controlled trials submitted for publication in Archives of Surgical Research must include a completed

Consolidated Standards of Reporting Trials (CONSORT) flow-chart and ensure that all features of the CONSORT checklist are present. A copy of the CONSORT checklist must be uploaded in supplemental material. Refer to the CONSORT statement website here.

Systematic Reviews

Systematic reviews are to be reported in accordance to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Guidelines and must include the flow-chart as a figure and the checklist as a supplemental material. Please download a PRISMA Flowchart and a PRISMA Checklist here. To aid and improve the methodological quality of your article, include an AMSTAR 2 checklist as well, which is available here.

Cohort, Case-control and Cross-sectional studies

Cohort, Case-control and Cross-sectional studies must be compliant with the STROCSS criteria (Strengthening the reporting of cohort studies in surgery), which is available here. Cite the following paper: Agha RA, Abdall-Razak A, Crossley E, Dowlut N, Iosifidis C, Mathew G, for the STROCSS Group. STROCSS 2019 Guideline: Strengthening The Reporting Of Cohort Studies in Surgery. Each study type has its own checklist which must be uploaded as supplemental material.

Diagnostic, Quality Improvement and Qualitative studies

Diagnostic studies should be reported according to the STARD statement criteria (Standards for the Reporting of Diagnostic Accuracy studies). The flow-chart should be a figure and checklist should be uploaded as supplementary material. Quality Improvement studies must comply with the Standards for Quality Improvement Reporting Excellence (SQUIRE) criteria, which is available here. Qualitative studies require the Consolidated criteria for Reporting Qualitative Research (COREQ) checklist, available here.

Health Economic Evaluation

Health Economic Evaluation studies should conform to the CHEERS statement, available here.

Tumour Marker Prognostic Study

Tumor Marker Prognostic studies should be reported according to the REMARK criteria.

Before and After Studies

Before and After studies measure specific characteristics of a population or group of individuals after an event or intervention, compare them with those characteristics before the event or intervention, then measure the effects of the event or intervention. These studies should conform to the STROCSS statement.

Experimental Animal Studies

Animal studies must be reported according to the ARRIVE guidelines (Animals in Research: Reporting In Vivo Experiments) and must include the checklist as supplemental material. An example of a completed checklist can be found here. The institutional protocol number must be included at the end of the abstract.

Qualitative Surveys

Qualitative Surveys should be reported according to the criteria detailed in the SRQR Guidelines. Guidelines for synthesis of qualitative research can be found here. Guidelines for interviews and focus groups are available here.

Case Series

Ensure that the case series is compliant with the PROCESS Guidelines and submit a completed PROCESS checklist. State that the work has been reported in line with the PROCESS criteria and cite the following paper: Riaz A. Agha, Mimi R.Borrelli, Reem Farwana, Kiron Koshy, Alex Fowler, Dennis P. Orgill, for the PROCESS Group. The PROCESS 2018 Statement: Updating Consensus Preferred Reporting Of CasE Series in Surgery (PROCESS) Guidelines.

Article Structure

Title Page

The title page should give the title in capital letters and a shorter running title. Avoid abbreviations and formulae if possible. In addition, the title page should also include:

- Correctly spelled names of all authors, and their affiliation addresses where the actual work was done. Include the e-mail address of each author.
- Signpost clearly the correspondence author who will maintain contact at all steps of reviewing and publication, and post-publication, and answer any questions about the research. All information must be updated in case of any changes.
- Present/permanent address of every author.
- The source of funding of the research.
- The number of figures and tables, the total word count and the total number of pages of the manuscript.
- A sample Title Page has been uploaded on this page above.

Abstract

All original articles must accompany a structured abstract of up *to 250-350* words. It should state aims of the study, methodology and materials used, results obtained, and conclusions reached. Specify how the sample selection of study subjects or experimental animals was carried out, specify the observational and analytical methods, and give specific data and its statistical significance, where possible. Highlight novel and significant aspects of the study. Avoid references, but if necessary, cite the author(s) and year(s). Avoid non-standard or uncommon abbreviations, but if necessary they must be defined at their first mention in the abstract. This page should constitute of the abstract and keywords only.

Keywords

Right after the abstract, provide a maximum of *6* keywords, using British spelling. Avoid general and plural terms and

multiple concepts (avoid, for example, 'and', 'of'). Only abbreviations firmly established in the field may be appropriate. These keywords will be used to aid the indexing process of the journal.

Introduction

Outline the aims of the work and provide sufficient background information, avoiding a lengthy literature review or a summary of the results.

Methodology

Provide adequate details to allow the research to be reproduced by an independent researcher. If experimental apparatus is used, the manufacturer's name and address should be included in parentheses. Methods that have previously been published should be summarized, and signposted by a reference. If quoting directly from a previously published method, use quotation marks and cite the source. Any alterations to existing methods should also be described. If a drug is used, its common name, dose and route of administration must be included. For patients, age and sex with mean age ± standard deviation must be given where relevant to the data. Statistical methods employed for comparisons of data sets must be mentioned and any computer programs used for calculations must be specified.

Results

Results should be clear and succinct. They must be presented in the form of text, tables and illustrations. The content of the tables should not be repeated in the text; the tables should be numbered and identified and referenced to as their number. A conclusion that either supports or negates the hypothesis should be included. If the data is inconclusive, that should also be noted.

Discussions

This should emphasize present findings of the research, and the differences and similarities with prior work done in the field by other researchers. Data must not be repeated in the discussion, and lengthy citations and reviews must be avoided. Highlight the original and central aspects of the study and the conclusions that they lead to.

References

Please make sure that Mendley or some other software is used for referencing. The articles without compliance in this area would be sent back. **American Medical Association (AMA Referencing Style) should be used.** References should be typed in sequential numbers in superscript for in-text citations, and numbered sequentially in the Reference List provided at the end. Maximum references for original article should not exceed 40; they should not exceed 10 for case reports, and 80 for reviews. Authors should ensure that locally published studies are given precedence. Add DOI number of documents where it is available.

References from books should include author, title, publisher, and year of publication. Example:

Das JC. *Power System Harmonics and Passive Filter Designs*. John Wiley & Sons, Inc; 2015.

For articles in journals, the authors, title of article, name of journal, year of publication, and an article identifier and page range (where available) must be included. See the following example:

Zhu Z, Hoffman JE. Condensed-matter physics: Catching relativistic electrons. *Nature.* 2014;513(7518):319-320.

Websites that are blogs and subject to changes by the author must be used as sparingly as possible, and when included, the author's name, the title, the name of website, date of publication, date on which the website was accessed, and a link to the website must all be included. Example:

Andrew E. After Years Of Conflict, Huge Project Could Help Scientists Decipher The Brain. IFLScience. Published June 18, 2015. Accessed October 30, 2018. https://www.iflscience.com/brain/after-years-conflict-huge-project-could-help-scientists-decipher-brain/

For government reports, technical reports, and scientific reports, if the report number is unavailable, then cite the report as a book. For reports it is usually not individual people that are credited as authors, but a governmental department or agency. Include the name of the agency, the title of the report, the publisher, and the year of publication. An example is as follows:

Government Accountability Office. *The Manager, the Government, and the Accounting Profession*. U.S. Government Printing Office; 1968.

References to Ph.D. dissertations, Master's theses or Bachelor theses follow the format outlined below, and must include author, title, publication detail if applicable, and year of publication.

Campbell AJ. History transformed: Sengoku Daimyo in Japanese popular media. Published online 2012.

For newspaper articles, citation must include the author, title, name of newspaper, full date and page number. The example is as follows:

Kinsley M. Paid Leave Counts as Progress. *New York Times*. May 27, 2017:SR3

Avoid referencing personal communications and unpublished observations, but they must be presented in parentheses in the text if included, and not in the list of references in the appendix. A research article may not be cited as "Under Publication" or "In Press" unless it has been accepted for publication. In such a case, the name of the journal must be given.

Acknowledgements

All contributors who do not meet the criteria for authorship should be credited in this section. It should include persons who provided technical help, writing assistance and general support or supervision. Financial and material assistance must also be credited. Persons who have added to the material but do not justify authorship can be listed as "clinical investigators", "participating investigators", "scientific advisors", "reviewers', or "data collectors."

5. FURTHER CONSIDERATIONS

World Limits

Maximum length of the original manuscript should not exceed *4000* words including title page, table and references. For review articles, the maximum word count is *3500,* however considering the demand of the subject it can be up to 8000 words. Maximum number of tables & illustrations should not exceed 5. Short reports of cases, clinical experience, drug trials and their adverse effects can be submitted. Maximum length of these case reports should not exceed *800* words, *5* maximum number of references, and *2* table or illustrations. For letters, maximum words are *600* with *5* references. Extra charges will be applicable for lengthy manuscripts.

Units, Abbreviations and Formulae

Système Internationale (SI) units should be used, with the traditional equivalent in parentheses where appropriate. Avoid non-standard or uncommon abbreviations, but if necessary they must be defined at their first mention. Submit math equations as editable text. Add simple formulae in line with normal text where possible and use the solidus (/) instead of a horizontal line for small fractional terms, e.g., X/Y. Variables are to be written in italics. Powers of e should be denoted by exp. Any equations that have been presented separately from the text (if referred to explicitly) must be numbered consecutively.

Artwork

Make sure to use uniform lettering and sizing of original artwork. For original illustrations, use Arial, Courier, Times New Roman, Symbol, or a font that looks similar. Number the illustrations according to their order in the text with a logical naming convention for the artwork files. Provide captions to illustrations separately. Size the illustrations close to the desired dimensions of the published version, avoiding any files that are disproportionately large. Submit each illustration as a separate file. If the electronic artwork is created in a Microsoft Office application (Word, PowerPoint, Excel) then please supply in the native document format without alterations or conversions. If the application used is not part of Microsoft Office, convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):

- EPS (or PDF): Vector drawings, make sure to embed fonts.
- TIFF (or JPEG): Color or gray-scale photographs (halftones); ensure a minimum of 300 dpi.
- TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings; ensure a minimum of 1000 dpi.
- TIFF (or JPEG): For combinations of bitmapped line/half-tone (color or gray-scale), ensure a minimum of 500 dpi.

Do not supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); these typically have a low number of pixels and limited set of colors. Do not supply files that are too low in resolution. Ensure that each illustration has a separate caption that is not attached to the figure. A caption should comprise of a short title and a brief description of the illustration. Avoid text in the illustrations themselves but explain the symbols and abbreviations used.

Tables

Submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or separately at the end in an appendix. Number tables consecutively according to their sequence in the text and present any table notes below the table body. Keep the use of tables to a minimum and ensure that the data included in them is not repeated in results described elsewhere in the article. Avoid using vertical rules and shading in table cells.

Supplementary Material, Research Data, and Video

Supplementary material such as applications, images, and sound clips, can be published with the article to enhance it. Submitted supplementary items are published exactly as they are received (Excel or PowerPoint files will appear as such online). Submit this material with the manuscript and supply a concise, descriptive caption for each file. If you want share data that supports your research publication, where appropriate, interlink the data with the article. Research data refers to the results of experimentation that validate research results. To enable reproducibility and data reuse, share the software, code, models, algorithms, protocols, methods and other useful materials related to the project. If you have made your research data available in a public data repository, link the dataset directly into your article. To enable transparency, we require you to state the availability of data in your submission if your data is unavailable to access or unsuitable to post. Authors who wish to submit video files with their article are encouraged to include links to these within the body of the article. This can be done in the same way as a figure or table by referring to the video or animation content and noting in the body text where it should be placed, or separately at the end. Keep the file in one of the recommended file formats with a preferred maximum size of 150 MB per file, 1 GB in total.

6. AFTER COMPLETION

Proofreading

Final version of the article is sent to corresponding author for proof reading before publication. In case of changes, corrections should be sent to the editor by email.

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Those who cannot pay for processing and publication can apply for waiver at the time of the submission of their article.

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Letter of Undertaking

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Printed Copy

One printed copy will be sent to the correspondence author. Authors can order additional copies at the rate of *cost*. Payment for additional copies should be sent in with the publication charges.

Submission

All manuscripts must be Word documents.

Ombudsperson

The journal's managing Editor can be contacted by authors and other personnel in case any grievances should arise by e-mail.

7. PRIVACY POLICY

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When you have created an account on the http://archivessr.com, you can update your private information at any time through your account settings.

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If you are concerned about how your information is stored, please contact us by email at editor@archivessr.com

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Archives of Surgical Research follows the COPE Core Practices and ICMJE's *Recommendations to conduct, report, edit and publish Scholarly Work in Medical Journals*, and expected an ethical behavior from authors, reviewers and editors to follow guidelines. We also follow the Principles of Transparency circulated through WAME.

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Archives of Surgical Research (ASR) defines research & publication misconduct as follows:

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- Data falsification/fabrication : intentional misrepresentation of research results
- Conflict of interest: a conflict of interest exists when a manuscript's or journal's author, editor, reviewer have a financial or personal relationship that may influence their intentions or bias.
- Redundant publication : when a published work (or substantial sections from a published work) is/are published more than once (in the same or another language) without adequate acknowledgment of the source/cross-referencing/justification (https://publicationethics.org/category/keywords/redundant-publication)

Any allegations of misconduct brought to the journal's attention will be dealt with immediately and seriously. ASR

will not accept articles that violate research & publication ethics, any manuscript not in compliance will be rejected.

ASR utilizes Turnitin to assess all submitted manuscripts, a plagiarism percentage upwards of 24% is unacceptable and articles not in accordance with this rule will be rejected.

In cases of citation manipulation, relevant COPE guidelines will be followed.

In case of suspected data falsification/fabrication, respective authors will be asked to clarify and explain their methods. Failure to do so will result in:

1. rejection of their submitted manuscript
2. communication of the authors' misconduct will be made to relevant institutions and regulatory bodies
3. black-listing of the authors from ASR for all future submissions

This is in accordance with COPE guidelines.

We follow the COPE Guidelines for sharing information regarding any misconduct with other journals. We also follow the COPE Retraction Guideline. We as a journal have policy to refer such cases to COPE if required.

In case of suspicion of image manipulation in a manuscript, COPE flowchart will be followed.

In cases of redundant publications, COPE flowchart will be followed.

Disclosures

All authors are required to submit a Disclosure of Interest form, which can be found here: http://www.icmje.org/disclosure-of-interest/. In case of an undisclosed conflict of interest, COPE guidelines will be followed.

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ASR implements ICJME recommendations for what constitutes authorship of a manuscript.

If a contributor does not fulfill the authorship criteria, ASR encourages listing them in the acknowledgements section. **All** authors are required to submit a Disclosure of Interest form, which can be found here: http://www.icmje.org/disclosure-of-interest/. In addition to submitting a disclosure of interest form, the manuscript must outline the specific contribution of each author. ASR Authors are also encouraged to link their ORCiD profiles.

Authorship disputes should be brought to light via email to relevant editors. They are handled through COPE Guidelines.

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As per ICMJE guidelines the authorship should be based on the following criteria:

1. Substantial contributions to conception & design, or acquisition of data, or analysis & interpretation of data.
2. We do not allow ghost, guest and gift authorships and if found so we follow COPE guidelines to handle such cases.
3. Drafting the article or revising it critically for important intellectual content.
4. Final approval of the version to be published. All those who meet the above three conditions are eligible to be included as Authors in the manuscript
5. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
6. When a large multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above. Acquisition of funding, collection of data, general supervision of the research group does not qualify any one to be an author. All contributors who do not meet the criteria for authorship should be listed in the acknowledgment section. Those who provide technical support, writing assistance, or department chair who provided just general support should also be mentioned in acknowledgment. It is also important that all those whose names appear in acknowledgement must have given permission to be acknowledged.

ICMJE http://www.icmje.org

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Archives of Surgical Research (ASR) follows COPE guidelines in case of appeals to the journal's editor's decisions and complaints about ASR's journal management of the peer review process.

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Furthermore, Archives of Surgical Research (ASR) consults COPE guidelines if a reviewer is suspected of appropriating or mismanaging author material and may refer such cases to COPE if required.

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Archives of Surgical Research (ASR) follows ICMJE data sharing guidelines.

In case of suspected data falsification/fabrication, respective authors will be asked to clarify and explain their methods.

To Improve transparency, we encourage use of and link to international standard reporting guidelines such as those listed in the EQUATOR Network. We encourage pre-registration of clinical trials (and other study designs) in an online clinical study database before data are collected (eg, ClinicalTrials.gov). We encourage journal pre-registration and peer review of study protocols before data are collected (eg, as promoted by the Center for Open Science).

We have system of scruitiny to find such data manipulations, if found may result in:

1. Rejection of their submitted manuscript
2. Communication of the authors' misconduct will be made to relevant institutions and regulatory bodies
3. Black-listing of the authors from ASR for all future submissions

This is in accordance with COPE guidelines.

In case of suspicion of image manipulation in a manuscript, COPE flowchart will be followed.

Ethical Oversight

Archives of Surgical Research (ASR) follows COPE guidelines for ethical oversight, wherever applicable. ASR has it's own consent form for case reports, which is mandatory along with the submission of the manuscript. The consent form is adapted from BMJ Case Reports and is in line with COPE guidelines. To determine whether a study requires ethical approval or not, ASR looks to COPE guidelines.

Furthermore, ASR requires a transparency declaration from the lead author of an original study guaranteeing honesty and accuracy (as published & implemented by the BMJ and endorsed by the EQUATOR network).

Post-publication Review and Audit

If authors whose work has been accepted and/or published wish to retract/correct/revise their articles, please email: editorial@archivessr.com, with the subject heading mentioning "RETRACTION" or "CORRECTION" or "REVISION".

Conflict of Interest Policy

Adopted from Conflict of Interest in Peer-Reviewed Medical Journals which is prepared by WAME Editorial Policy and Publication Ethics Committees.

Articles would be published with statements or supporting documents declaring:

Authors' conflicts of interest

Sources of support for the work, including sponsor names along with explanations of the role of those sources if any in study design; collection, analysis, and interpretation of data; writing of the report; the decision to submit the report for publication; or a statement declaring that the supporting source had no such involvement; and Whether the authors had access to the study data, with an explanation of the nature and extent of access, including whether access is on-going.

To support the above statements, editors may request that authors of a study sponsored by a funder with a proprietary or financial interest in the outcome sign a statement, such as "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis."

Disclosure form is available from the website, which has been adapted from ICMJE Disclosure Form and should be filled at the time of acceptance of manuscript. Disclosures are also obtained whenever deemed necessary at the time of review and editorial tasks.

9. EDITORIAL POLICIES

Principles of Transparency and Best Practice in Scholarly Publishing are followed as per ICMJE guidelines. This Journal strives to adhere to the ***Principles of Transparency and Best Practice in Scholarly Publishing*** which could be found in the **DOAJ** Web site completely,

This Journal has established a guideline for editorial independence as delineated below. The guideline generally follows that created by the World Association of Medical Editors.

1. This Journal is operated by Pakistan Endocrine & Thyroid Surgeons Association (PETSA), which is publishing organization.
2. The Chief Editor is responsible for independent leadership of This Journal editorial operations. The General Publishing Editor reports to the Editor-in-Chief for all editorial matters.
3. The Editor-in-Chief has full authority over the content of this Journal and its related offerings. This includes summaries and comments on recent medical advances, opinions, blogs and news.
4. Content-related decisions are based on quality, importance, and value to the users of this Journal. Contributing authors, editors, This Journal staff are free to express responsible positions -even if these views are not in agreement with interests, policies or published research, editorial or commentary of PETSA.
5. This Journal actively seeks input regarding editorial matters from the physician Editors-in-Chief in an advisory capacity, as well as from the other editorial board members, internal editorial staff, and readers.
6. Editors-in-Chief of this Journal is empowered to create content and commentary free of commercial and organizational influence. All authors and editors operate without conflict of interest and all potential conflicts are disclosed (please also see Conflict of Interest Policy).

10. PEER REVIEW POLICY

We follow ICMJE recommendations on the manuscript handling. The practice of peer review is to ensure that only good science is published. It is an objective process at the heart of good scholarly publishing and is carried out by all reputable scientific journals. Our referees play a vital role in maintaining the high standards Review Policy and all manuscripts are peer reviewed following the procedure outlined below:

Initial manuscript evaluation

The Editor first evaluates all manuscripts. It is rare, but it is possible for an exceptional manuscript to be accepted at this stage. Manuscripts rejected at this stage are insufficiently original, have serious scientific flaws, have poor grammar or English language, or are outside the aims and scope of the journal. Those that meet the minimum criteria are normally passed on to at least 2 experts for review. Most of the submitted manuscripts are reviewed except few invited or editorial content.

Type of Peer Review

Policy employs double blind reviewing, where both the referee and author remain anonymous throughout the process.

How the Referee is selected

Whenever possible, referees are matched to the paper according to their expertise and our database is constantly being updated. The referee is selected both from the editorial team and outside and depending on the author suggestions.

Referee Reports

Referees are asked to evaluate whether the manuscript: - Is original - Is methodologically sound - Follows appropriate ethical guidelines - Has results which are clearly presented and support the conclusions - Correctly references previous relevant work. This is a systematic process and works on the well-designed Peer Review Proforma. The confidentiality of the peer review is ensured. Reviewers are encouraged to report conflict of interest, ethical misconduct etc.

Language correction is not part of the peer review process, but referees may, if so wish, suggest corrections to the manuscript.

How long does the review process take?

The time required for the review process is dependent on the response of the referees. Should the referee's reports contradict one another or a report is unnecessarily delayed, a further expert opinion will be sought. The Editor's decision will be sent to the author with recommendations made by the referees, which usually includes verbatim comments by the referees. Revised manuscripts might be returned to the initial referees who may then request another revision of a manuscript.

Final Report

A final decision to accept or reject the manuscript will be sent to the author along with any recommendations made by the referees, and may include verbatim comments by the referees.

Editor's Decision is Final

Referees advise the editor, who is responsible for the final decision to accept or reject the article.

Conflict of Interest

All reviewers and editors have to declare any potential conflicts of interest if any. We follow COPE and ICMJE guidelines in this regard.

Editorial and Peer Review Processes Generally Follow these Steps:

We follow and request from authors, reviewers and editors the "ICJME Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals". Editorial reviewer policy is independent of any financial, academic or any other interest.

- When an article is submitted to Archives of Surgical Research, Editor makes the first check of submitted articles (structure, plagiarism, scientific quality).
- Article may be rejected, sent back for structural revision, or sent to at least two reviewers for peer review.
- After peer review process, articles may be rejected, sent back for revision requested by reviewers or accepted for publication.
- Revised articles by authors may be accepted, resent to reviewers, resent to authors for additional corrections/revision or rejected.
- Authors could not see reviewers' information. Editor may make authors' information available to reviewers or not.
- Accepted articles are forwarded to publishing process.
- Editor(s) may require additional materials or changes from authors during copy editing, composing, grammatical editing and/or proof reading steps.
- A fast track review system is in place upon deposition of additional processing fee (Rs. 20,000), however we do not encourage such route and should be employed only in significant circumstances. Moreover, this does not ensure that manuscript if accepted would be published on priority.
- Post-publication review and peer review is encouraged and is managed through letter to the editors.

11. STATEMENT OF INFORMED CONSENT

We follow ICMJE and COPE Guidelines for appropriate consenting. Patient's privacy should not be breached without taking consent. In written descriptions there should not be any specifications regarding patients including names, hospital numbers, photographs or pedigrees unless the information is needed for scientific purposes and the patient

allows for publication with written informed consent. It should be disclosed by authors to the patients that any identifiable material could be available on the Internet or in printed form after publication. Patient consent ought to be written and archived with the journal, the authors, or both, as settled by local rules and regulations. Applicable laws vary from territory to territory, and journals should make their own policies with legal guidance. Since a journal that archives the consent will be aware of patient identity, some journals may decide that patient confidentiality is better guarded by having the author archive the consent and instead providing the journal with a written statement that attests that they have received and archived written patient consent.

Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate protection of anonymity. If identifying characteristics are de-identified, authors should provide assurance, and editors should so note, that such changes do not distort scientific meaning.

The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained, it should be indicated in the published article.

- International Committee of Medical Journal Editors ("Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals")

12. GUIDELINE FOR REVIEWERS

Peer review in all its forms plays an important role in ensuring the integrity of the scholarly record. The process depends to a large extent on trust, and requires that everyone involved behaves responsibly and ethically. Peer reviewers play a central and critical part in the peer-review process, but too often come to the role without any guidance and unaware of their ethical obligations.

Archives of Surgical Research follows COPE Guidelines for educating the reviewers for the review process.

13. ETHICAL EDITING FOR EDITORS

Becoming an editor of Archives of Surgical Research is an exciting but daunting task, especially if you are working alone without day to day contact with editorial colleagues. This short guide aims to summarize key issues and to provide links to relevant pages of the COPE website as well as those of other organizations. We encourage the editorial team to consult COPE and ICMJE resources frequently for their training and handling of the manuscript and various editorial issues.

14. GUIDELINES FOR JOURNAL MANAGEMENT

We believe that Archives of Surgical Research serves as an important part of the scientific literature. Hence, its management should be of the highest quality and ethically sound. We follow COPE Guidelines to manage the top hierarchy in terms of conflicts of interest and ethical considerations. We also following COPE Guidelines for maintaining relationship of journal management to the Pakistan Endocrine & Thyroid Surgeons Association to ensure editorial independence. The journal editorial teams meets periodically at least biannually. The editorial team is independent of the society and is managed by a transparent process two yearly as per the ethical confines suggested by COPE, ICMJE and local guidelines.

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Definitions:

- *"preprint" - a version of an article created prior to peer review*
- *"accepted author manuscript" - an author-created version of the final journal article (to reflect changes made in peer review and editing)*

"publisher-created version" - the definitive final record of published research that appears in the journal and embodies all value-adding publisher activities including copy-editing, formatting and pagination.

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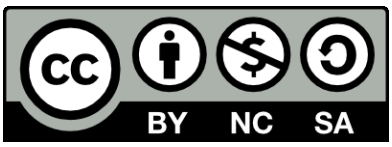

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