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Observation Versus Gel-Foam Grafting of Acute Traumatic Tympanic Membrane Perforation: Which Is Better?

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ABSTRACT

Background: This study aimed to compare between 2 methods of recent traumatic tympanic membrane (TM) perforation management (observation and gel-foam patching).

Methods: The patients with recent traumatic TM perforation (within 3 months) were divided into 2 groups (one group managed by observation and other group managed by gel-foam patching) with 3-month follow-up period. The comparison factors are healing rate, healing time, and air–bone gap (ABG) closure in healed cases.

Results: There are 62 ears with perforation of TM, 30 ears treated by observation method, and 32 ears treated by gel-foam grafting, healing rate is higher in second group (84.3%) and healing time is shorter in second group; these differences are not significant statistically with *P*-values equal to (.168), (.494) consecutively; in addition, ABG closure was same in both groups.

Conclusion: Healing rate when use gel-foam patching for acute TM perforation is higher than observation without any manipulation but really this difference is not significance statistically. The time that needed for healing is less in patients who undergone gel-foam patching in comparison with observational methods; thus will decrease number of patients who may complain from complications of TM perforation, as well-known earlier healing lead to earlier return to normal personal activities, but also this difference is not statistical significant. There is no difference in ABG closure in both types of management.

Keywords: Tympanic membrane perforation, gel-foam, myringoplasty, air–bone gap

Introduction

Tympanic membrane (TM) perforation is a condition as old as the human species.[1] Traumatic perforations often occur in healthy members of the community with an excellent general prognosis.[2] However, small perforations are more likely to close spontaneously than large ones; the 2 main factors leading to the failure of the perforations to heal are loss of tissue and secondary infection.[3]

The eardrum tends to heal itself and the principal that leads to the healing of perforated TM is epithelial migration toward the center of the perforation. After trauma, the TM thickens as a result of edema, inflammation, and neo-vascularization.[4-6] A perforation heals with a thin membrane consisting only of mucosal and squamous epithelial layers without a fibrous middle layer. Such a neo-membrane may be so thin that it can be mistaken for a perforation instead of a healed perforation. Neo-membranes may retract deeply into the middle ear, sometimes making them more difficult to distinguish from actual perforations. If bacteria-contaminated water passes through the perforation, infection can result.[7]

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The perforation could be central (doesn't involve the tympanic annulus) or marginal (involves the tympanic annulus). The marginal perforation is more likely to develop epidermal growth than the central type. The central TM perforation either heals or persists, it is suggested that central TM perforations that persist for long time may develop cholesteatoma or tympanosclerosis.[8,9]

Infection is the principal cause of TM perforation. However, there are traumatic causes of TM perforation, including the insertion of objects into the ear canal, either purposely or accidentally, concussion caused by an explosion or open-handed slap across the ear, head trauma, sudden negative pressure, barotrauma (during air travel or scuba diving), and iatrogenic perforation during irrigation or foreign body removal.[2,3,10]

Tympanic membrane perforation is classified according to size into ***Grade 1*** is less than 25% of TM; ***Grade 2*** is 25-50% of TM or multiple perforations involving 2 quadrants of TM; ***Grade 3*** is 50-75% or multiple perforations involving 3 quadrants of TM; and ***Grade 4***, which is more than 75% or marginal perforation.[11]

Complications of traumatic TM perforations are hearing loss, middle ear infection (otitis media), and middle ear cholesteatoma.[12-14]

Treatment of acute traumatic TM perforation is either treating the perforations by observable methods or simple outpatient clinic procedures:

Observable Method

Small and slit-like TM perforations have the potential for spontaneous healing within a few days. To allow healing, the ear must be kept dry and blowing the nose must be avoided. Unless there is acute otitis media, there is no need for topical or systemic antibiotics.

Simple Outpatient Clinic Procedures

Using different materials has been tried to close TM perforation in an attempt to enhance and fasten the healing process of TM perforation. A small patch of fine paper (cigarette paper) or gel-foam can be directly applied over the perforation and held in these positions by antibiotics pomades or a small amount of the patient's own patient blood. These patches act as a scaffold for regenerating outer squamous epithelium, providing bridges to ends of the perforation and prevent their movement toward the inside of the middle ear. Gel-foam patching itself can stimulate the inflammatory response and accelerate healing. Other materials like topical hyaluronic acid, chlortetracycline ointment, and epidermal growth factor can be applied directly on the perforation of the TM to enhance the healing.[10,15-21]

Immediate surgical procedures using tympanoplasty techniques are not indicated for acute TM perforation because of the high closure rates within 6 months, even reaching to 90% without surgical myringoplasty. If the perforation of the TM failed to be healed and closed (mainly due to loss of tissue, such as a large perforation, secondary infection, or both) during the 6-month period, then we can do surgical myringoplasty.[2,3,22]

The aim of the present study is to compare 2 methods of treating recent traumatic TM perforation (observation method and gel-foam patching) based on healing rate, healing time, and complete closure of the air–bone gap (ABG) for healed cases.

MAIN POINTS

- *Recent traumatic TM perforation is either treated by observation or by placing some material on the perforation by otolaryngologists.*
- *Healing rate when using gel-foam patching for acute TM perforation is higher than observation without any manipulation.*
- *There is no difference in the closure of ABG in both types of management.*
- *The time needed for healing is less in patients who undergo gel-foam patching compared to observational method.*
- *These outcomes will decrease the number of patients who may complain of complications of tympanic membrane perforation and as well-known earlier healing leads to earlier return to normal personal activities.*

Material and Methods

Setting and Study Design

A prospective comparative clinical trial study was executed in the ear, nose, and throat department of Al-Shahid Ghazi Al-Hariri Hospital for Surgical Specialties and Al-Yarmouk Teaching Hospital from October of 2021 to December of 2022.

Ethical Consideration

The ethical approval was obtained from the University of 'Al-Qadisiyah administrations (Approval Number: 113, Date: 5/10/2021). The details of this work were explained to the patients and their families, and written informed consent was taken.

Inclusion and Exclusion Criteria

This study was conducted in patients aged 15-60 years old who had TM perforation due to trauma within a period of less than 3 months for various reasons (variable types of trauma causing the perforations).

While patients who had acute otitis media or acute otitis externa and who suffered from temporal bone fractures or life-threatening condition were excluded.

Sampling

The patients, who fit the inclusion criteria and visited the consultancy clinics during the period of the present study, were enrolled.

Procedure

The total number of selected patients was 55, divided randomly into 2 groups: group A (27 patients), who are treated by the observation method, and group B (28 patients), who were treated by gel-foam patching (grafting perforation by gel-foam piece).

Workup for Group A: The number of patients in group A was 27; (3 of them had bilateral TM perforations, so the total number of perforations was 30 in this group).

Cleansing of their external auditory canal was performed, followed by an examination of the ear using an otoscope and microscope done to diagnose perforation. Baseline pure tone audiometry (PTA) was conducted within few days of first attendance (the patients were advised to avoid nasal blowing, take precautions for water protection, and they were prescribed amoxicillin capsules 500 mg 3 times daily for 1 week).

The follow-up of group A with the following visit protocol: the first visit is 1 month after the start of observation, the second visit is 2 months after the start, and the third visit is 3 months after the start (if

healing observed at the first or second visit, there is no need for the next one). At every visit, an examination was done using an otoscope and microscope (if healing occurs, a PTA done). If the perforation is preceded by acoustic trauma, a second PTA was done after 3 weeks even if no healing is observed. The patients were instructed to return to the hospital at any time when they develop ear discharge to be prescribed antibiotics.

Workup for Group B: The number of patients in group B was 28, but 4 patients had bilateral TM perforation, so the perforation number in this group was 32.

Cleansing of the external auditory canal with examination of the ear using an otoscope and microscope with doing baseline PTA. Local anesthesia (2% lidocaine) is then applied in the ear canal. Afterward, a piece of gel-foam slightly larger than the size of the perforation is applied on the perforation and it is impregnated with a blood droplet taken from the same patient to facilitate adhesion. The gel-foam is then immediately applied on the perforation through trans-canal approach without approximating the edges of perforation and there must be insurance to cover all perforation edges. Gel-foam is in direct contact with the TM and at the end of the procedure, there is no insertion of ear pack.

Here, the same advices of water precautions and avoidance of nasal blowing was given to the patients. They were also prescribed Amoxicillin capsules 500 mg 3 times daily for 1 week.

The follow-up is the same for group A but when gel-foam is noticed to be extruded during the follow-up, a new piece is replaced. The patients of this group were informed to return to the hospital at any time they develop ear discharge to remove the gel-foam and to be treated with antibiotics.

Perforation was classified according to the size by the same pattern in both of the groups as follows:

- *Grade 1* is less than 25% of TM.
- *Grade 2* is 25-50% of TM or multiple perforations involving 2 quadrants of the TM.
- *Grade 3* is 50-75% of TM or multiple perforations involving 3 quadrants of the TM.
- *Grade 4* is more than 75% of TM or marginal perforation.

Statistical Analysis

The data has been managed and analyzed with Statistical Package for the Social Sciences computer software v.24.0 (IBM SPSS Corp.; Armonk, NY, USA). The Chi-square test was applied to define the association between the categorical variables. A confidence level of 95% with a *P*-value ≤.05 was considered significant.

Results

The total number of patients was 55; 27 patients in group A and 28 patients in group B (in group A, 3 patients had bilateral perforations, bringing the total to 30 ears in this group), while in group B there were 4 patients had bilateral perforations, bringing the total to 32 ears presented in that group.

The ages of patients included in this study ranged from 15 to 60 years, with a mean of 33.95 ± 32 standard deviation. In group A, age of 6 conditions (6 patients) was below 20 years (20%); the age of 16 conditions (14 patients, but 2 of them had bilateral perforations) ranged from 20 to 40 years (53.4%), and age of 8 conditions (7 patients, but one of them had bilateral perforations) ranged from 40 to 60 years (26.6%). In group B, age in 5 conditions (4 patients, but one of them had bilateral perforations) was below 20 years (15.6%); age in 15 conditions (13 patients) ranged from 20 to 40 years (46.9%), and age in 12 conditions (11 patients) was 40-60 years (37.5%).

In the present study, there were 35 (63.6%) male patients and 20 (36.4%) were female. In group A, 16 (59.25%) patients were male (3 of them had bilateral perforations) and 11 (40.75%) patients were female. In group B, 19 (67.85%) were male (4 of them had bilateral perforations) and 9 (32.15%) were female.

The current study found that blast injury was the most common cause of TM perforation, with 30 patients and percentage of 48.4%. In group A, 14 perforations were due to blast injuries (46.7%), while 6 perforations due to slap injury (20%), and 10 perforations due to other injuries (33.3%). In group B, 16 perforations were due to blast injury (50%), 5 perforations due to slap injury (15.6%), and 11 perforations due to other injuries (34.4%).

Right- and left-sided TM perforations were equally reported in this work with 24 perforations on each side (43.6%), while bilateral perforations occurred in 7 patients (12.8%). In group A, 16 of perforations were on the right side (53.3%), while 14 perforations were on the left side (46.7%). In group B, 15 perforations were on the right side (46.9%), while 17 perforations were on the left side (53.1%).

Regarding the size of TM perforation, it is arranged into 4 grades:

- *Grade 1*; 26 perforations (41.9%).
- *Grade 2*; 21 perforations (33.9%).
- *Grade 3*; 10 perforations (16.1%).
- *Grade 4*; 5 perforations (8.1%).

In group A, 12 perforations were of *grade 1* (40%), 10 perforations were of *grade 2* (33.3%), 5 perforations were of *grade 3* (16.7%), and 3 perforations were of *grade 4* (10%). In group B, 14 perforations were of *grade 1* (43.75%), 11 perforations were of *grade 2* (34.4%), 5 perforations were of *grade 3* (15.6%), and 2 perforations were of *grade 4* (6.25%).

As shown in Table 1; only 3 patients (4.8%) developed acute otitis media: 1 patient in group A (1.6%) and 2 patients in group B (3.2%). All these cases ultimately failed to heal.

This study mentioned that the total healing rate was 84.3% and 70% in group B and group A, respectively. In group A: number of healed perforations of *grade 1* was 11 , (91.6%); in *grade 2* was 8, (80%); in *grade 3* was 2, (40%), and none in *grade 4* (0%). In group B, number of healed perforations in *grade 1* was 14, (100%), in *grade 2* was 9, (81.8%), in *grade 3* was 3, (60%), and 1 perforation in *grade 4* with a percentage of (50%).

Concerning the time of healing:

In group A, as shown in Figure 1.

a) *Grade 1*: 7 ears healed after one month and 4 after 2 months.
b) *Grade 2*: none of the ears healed after one month, 2 ears healed after 2 months, and 6 healed after 3 months.
c) *Grade 3*: both (2) ears fully healed after 3 months.

Table 1. Shows Frequency Distribution of the Sample Variables

Variable		Frequency	Percent (%)
Mean age in years 33.95 ± 3.2 SD (range 15-60) years			
Gender (n 55)	Male	35	63.6
	Female	20	36.4
Side of perforation (n 55)	Right	24	43.6
	Left	24	43.6
	Bilateral	7	12.8
Type of trauma (n 62)	Blast	30	48.4
	Slap	11	17.7
	Others	21	33.9
Grade of perforation (n 62)	I	26	41.9
	II	21	33.9
	III	10	16.1
	IV	5	8.1
Otitis media (n 62)	Yes	3	4.8
	No	59	95.2
Outcome (n 62)	Non-healing	14	22.6
	Healing	48	77.4

In group B, as shown in Figure 2.

a) *Grade 1*: 10 ears healed after 1 month, 3 ears healed after 2 months, and 1 ear after 3 months.
b) *Grade 2*: 1 ear healed after 1 month, 5 ears healed after 2 months, and 3 ears healed after 3 months.
c) *Grade 3*: 1 ear healed after 2 months and 2 ears healed after 3 months.
d) *Grade 4*: 1 perforation healed after 3 months.

As regards the closure of the ABG in healed cases:

In group A, as shown in Figure 3:

a) *Grade 1*: 2 ears of the healed group (2:11) did not have complete closure of the ABG.
b) *Grade 2*: 3 ears of the healed group (3:8) still have an ABG.
c) *Grade 3*: both healed cases still have an ABG.

In group B, as shown in Figure 4:

a) *Grade 1*: 1 ear of the healed group (1:14) still have ABG.

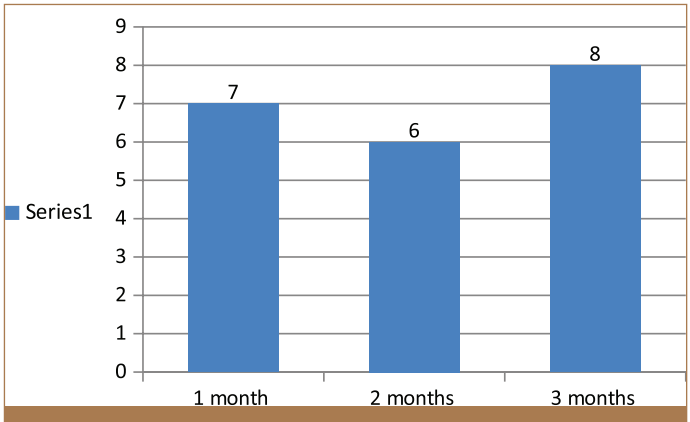

Figure 1. Frequency distribution of the healing time in group A.

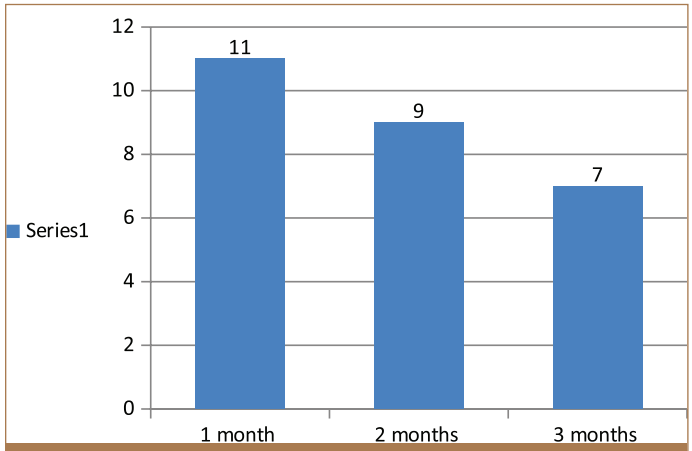

Figure 2. Frequency distribution of the healing time in group B.

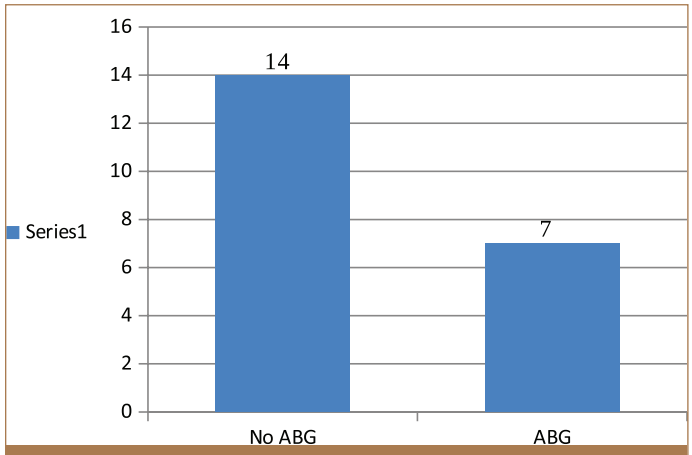

Figure 3. Frequency distribution of the air–bone closure in group A.

b) *Grade 2*: 4 ears of the healed group (4:9) still have an ABG.
c) *Grade 3*: All 3 healed cases still have an ABG.
d) *Grade 4*: still has an ABG.

Discussion

In this study, there is a large number of conditions in the age of 20-40 years in relation to other age groups, whether in group A or group B.

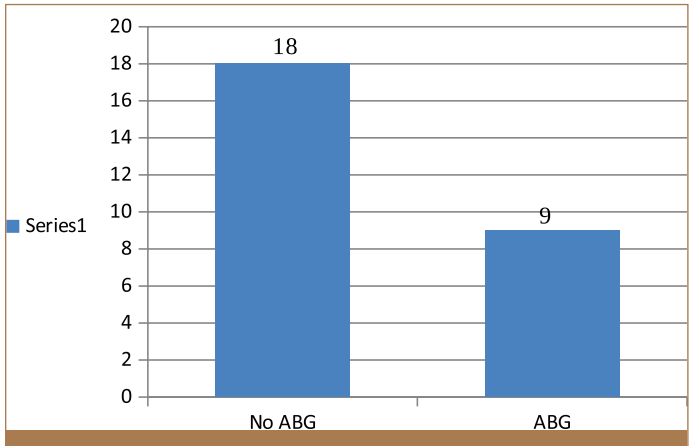

Figure 4. Frequency distribution of the air–bone closure in group B.

In group A, 6 ears (20%) below 20 years, 16 ears (53.4%) between 20 and 40 years, and 8 ears (26.6%) between 40 and 60 years. In group B, 5 ears (15.6%) below 20 years, 15 ears (46.9%) between 20 and 40 years, and 12 ears (37.5%) between 40 and 60 years. Perhaps it may be explained that the age of working group of the population and multiple physical activity groups is near this age, which matches with results of Ahmed Al-Juboori,[23] Lou et al,[24] and Salim.[25]

This research found that TM perforation occurred more in male than female patients in each group. In group A, 16 patients were male (59.25%), and 11 patients were female (40.75%). In group B, 19 patients were male (67.85%), while 9 patients were female (32.15%).

A large proportion of males explicated due to the nature of heavy activities of male and some of them work in military actions (so they are more prone to blast injuries). This agrees with works of Lou et al[24] and Afolabi et al[26] The most common type of trauma in both groups is blast injuries: 46.7% in group A and 50% in group B, and thus explained by the war of our army with the terror and bomb explosions in our cities.

One condition in group A developed ear discharge (3.3%) and 2 conditions developed ear discharge in group B (6.25%). Therefore, the proportion middle ear infection is slightly higher in group B but statistically not significant with a *P*-value = .252, opposing the study of Lou and He[27] which showed that the occurrence of middle ear infection is slightly higher in spontaneous healing.

Occurrence of acute otitis media may be excused by improper water precautions or upper respiratory tract infections and the rate of infection in group B is not much higher than in group A, which can be explained by the fact that gel-foam is a sterile substance.

In group A, the total healing rate was 70%, while healing rate was 91.6% in *grade 1*, 80% in *grade 2*, 40% in *grade 3*, and none in *grade 4*. Spontaneous healing rates of traumatic TM perforation were reported as 79%, 94%, 86%, 76%, and 71% in the research of Kristensen,[28] Orji and Agu,[29] Yamazaki and Sato,[30] Chun et al,[31] and Ozturk et al,[32] respectively. In group B, the total healing rate is 84.3%, while healing rate in *grade 1* is 100%, the healing rate in *grade 2* is 81.8%, the healing rate in *grade 3* is 60%, and healing rate in *grade 4* is 50%. In the present study, gel-foam patching resulted in an apparently higher healing rate 84.3% versus 70%, but unfortunately it is statistically not significant with a *P*-value = .168. This higher rate of healing in group B suggests a positive role for patching in the healing of traumatic TM perforation. This can be described by the fact that gel-foam patching may act as a scaffold to support squamous epithelium migration and promote perforated TM healing. Additionally, gel-foam patching itself can stimulate the inflammatory response and accelerate eardrum healing. In a study done by Mohammed Emad,[33] the overall healing rate by gel-foam patching was 87%, while Amadasun[34] mentioned no significant difference in the healing rate between spontaneous healing and paper patching.

In the existing work, it is important to notice the healing rate decreases in both groups, when the grade of perforation increases due to inability of proliferating epithelial cells to cover larger defects.

In both groups, it is apparent that larger perforations need more time for healing (explaining that proliferating cells need more time to close larger defects); however, in group B, perforations heal more

Table 2. Shows Distribution of the Management Type Within the Sample Variables

		Management				
Variable		**Observation**		**Gel-foam Patching**		***P***
Mean age in years		31.41 ± 12.53		36.39 ± 12.67		0.148(NS)
Gender (n = 55)	Male	16	45.7	19	54.3	0.508(NS)
	Female	11	55	9	45	
Side of perforation (n = 55)	Right	13	54.2	11	45.8	0.924(NS)
	Left	11	45.8	13	54.2	
	Bilateral	3	42.9	4	57.1	
Type of trauma (n = 62)	Blast	14	46.6	16	53.4	0.541(NS)
	Slap	6	54.5	5	45.5	
	Others	10	47.6	11	52.4	
Grade of perforation (n = 62)	I	12	46.2	14	53.8	0.656(NS)
	II	10	47.6	11	52.4	
	III	5	50	5	50	
	IV	3	60	2	40	
Otitis media (n = 62)	Yes	1	33.3	2	66.7	0.252(NS)
	No	29	49.1	30	50.9	
Outcome (n = 62)	Non-healing	9	64.2	5	35.8	0.168(NS)
	Healing	21	43.8	27	56.2	
Healing duration (n = 62)	Not healed	9	64.3	5	35.7	0.494(NS)
	1 month	7	38.8	11	61.2	
	2 months	6	40	9	60	
	3 months	8	53.3	7	46.7	
ABG after healing (n = 48)	No ABG	14	43.8	18	56.2	0.915(NS)
	ABG	7	43.7	9	56.3	

NS, not significant.

rapid to the same grades of perforations in group A (may be due to the suggestion that the facilitation of the healing process by the patching material acts as scaffold for proliferating cells), but it is also not significant with *P*-value of .494. As shown in Table 2.

The work by Lou and He[27] found a statistically significant difference in the time of healing of the TM between patients observed for spontaneous healing and patients treated by gel-foam patching. Also, Han, M.A. et al[35] suggested that paper patching could facilitate recovery, while traumatic TM perforation had no closure weeks after the injury, according to the results of Orji and Agu.[29]

In the current study, closure of ABG in both groups was not different. Failure of closure of the ABG in some conditions of healed perforations may be due to co-existing ossicular distortion caused by trauma itself or by some middle ear pathology before the exposure to trauma. Another explanation for persistent ABG is healed area of the TM does not have the same vibrational efficiency as a normal TM. Mohammed Emad[33] stated that 100% of healed *grade 1* perforations resulted in the disappearance of ABG, 55% of healed *grade 2* perforations resulted in complete closure of the ABG, while none of the healed *grade 3* perforations resulted in complete closure of the ABG.

Data Availability Statement: *The data that support the findings of this study are available on request from the corresponding author.*

Ethics Committee Approval: *This study was approved by the Ethics Committee of Al-Qadisiyah University (approval number: 113; date: 5/10/2021).*

Informed Consent: *Written informed consent was obtained from the patients and parents of the patients who agreed to take part in the study.*

Peer-review: *Externally peer reviewed.*

Author Contributions: *Concept – M.S.A.A., A.S.A.; Design – M.D.A., A.S.A.; Supervision – M.D.A., M.S.A.A.; Resources – M.D.A., M.S.A.A.; Materials – M.D.A., A.S.A.; Data Collection and/or Processing – M.S.A.A., A.S.A.; Analysis and/or Interpretation – A.S.A., M.S.A.A.; Literature Search – M.S.A.A., A.S.A.; Writing – A.S.A., M.S.A.A.; Critical Review – M.D.A., A.S.*

Declaration of Interests: *The authors have no conflict of interest to declare.*

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