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Research Article

Subscleral Trabeculectomy with Iris Incarceration in Buphthalmous

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Abstract

Purpose: To evaluate a new modification for surgical treatment of Buphthalmous using Subscleral trabeculectomy (SST) with iris incarceration.

Design: Prospective, randomized, consecutive interventional comparative study.

Setting: Ophthalmology department, Faculty of Medicine, Minia University, 61519, El-Minia, Egypt.

Patients and Methods: This was a prospective study of 40 eyes with Buphthalmous in 25 child (15 bilateral and 10 with unilateral Buphthalmous) divided into 2 groups. Group 1 (20 eyes) those underwent Subscleral trabeculectomy with iris incarceration and group 2 (20 eyes) underwent conventional rigid trabeculotomy through a period of 4 years between January 2015 and February 2019. Patient's data of 2 years follow-up were recorded. The primary outcomes were the mean intraocular pressure control in which complete success was defined as an IOP ≤ 18 mm Hg without the use of antiglaucoma drugs and a qualified success when medications were used to reach this target and the number of another surgical interference till reach IOP control. The secondary outcomes were studding, the change in corneal diameter, cup disc ratio and axial length.

Results: The mean IOP was reduced from 26.28 ± 0.73 to 13.32 ± 0.94 and from 26.52 ± 0.74 to 13.90 ± 0.98 at 2 years follow up visit in group 1 and group 2 respectively, but it had a tendency to be lower in group1 with significant difference at one week, 1 month and 3 months post-operative visits (p = 0.006, 0.005 and 0.03). A complete success rate was reached to 100% versus 40% and qualified success in 100% versus 50% and failure in 0% versus 50% in group 1 and group 2, respectively.

Conclusion: SST with iris incarceration was superior in controlling the IOP with first surgical interference, less complications and good visual function in comparison to trabeculotomy in which the eyes needed more surgical interventions. SST with iris incarceration is a safe surgical procedure and yielded good IOP control and excellent success rate in Buphthalmous.

Keywords: *Buphthalmous; Iris Incarceration; Sub-Scleral Trabeculectomy; Trabeculotomy*

Abbreviations

PCG: Primary Congenital Glaucoma; SST: Subscleral Trabeculectomy; MMC: Mitomycin c; AXL: Axial Length; IOP: Intraocular Pressure; SC: Schlemm's Canal; TM: Trabecular Meshwork; HCD: Horizontal Corneal Diameter; C/D: Cup Disc Ratio; GA: General Anesthesia; QID: Four Times/Day; TID: Three Times/Day

Introduction

Primary congenital or infantile glaucoma (Buphthalmous) is an inherited eye disorder that results from an isolated maldevelopment of the trabecular meshwork [1]. This condition usually manifests itself within the first year of life with a typical presentation of tearing, pho-

tophobia and corneal cloudiness. Surgery is the main and cornerstone in management of PCG. Combined trabeculectomy-trabeculotomy with Mitomycin c (MMC), is the most common surgery for PCG currently practiced [2]. However, the post-operative success of intraocular pressure (IOP) control ceases over time despite of an initial successful surgery due to disease progression, bleb failure with excessive flap fibrosis and Conjunctival scaring [3]. As previously failed filtering surgery is a known risk factor for surgical failure and hence the need for subsequent surgical intervention such as repeated trabeculectomy with MMC, aqueous shunt and cyclodestructive procedures [4]. The other surgical interference in PCG including Goniotomy which needs clear cornea, trabeculotomy of the inner wall of Schlemm's canal (SC) and adjacent trabecular meshwork (TM) either (manual, suture or microcatheter assisted) procedures are studied [5-9]. In spite of many studies of various antiglaucoma procedures to the best of our knowledge, no study has been published on this new modification of SST which we termed it (SST with iris incarceration). We conducted this prospective study to evaluate this new procedure efficacy and comparing its outcomes with trabeculotomy in Buphthalmous management.

Subjects and Methods

This was a prospective study of eyes of 40 eyes with Buphthalmous in 25 infants 15 males and 10 females (15 bilateral and 10 with unilateral disease) divided into 2 groups. Group 1 (20 eyes) those underwent Subscleral trabeculectomy (SST) with iris incarceration a new modification to SST and group 2 conventional rigid trabeculotomy through a period of 4 years between January 2015 and February 2019. The local board committee approved the study as well as all patients relatives signed a consent and the study was in agreement with Declaration of Helsinki Tents. The primary outcomes were the mean intraocular pressure (IOP) measured under General anesthesia (GA) and the number of repeated surgical interventions. A complete success was defined as an IOP ≤ 18 mm Hg without the use of antiglaucoma drugs, a qualified success when medications were used to reach this target and failure if the target IOP would not be reached in spite of full antiglaucoma medication and the infant needs another antiglaucoma procedure and the number of repeated surgical intervention were recorded. The secondary outcomes were studding the change in corneal diameter (CD), cup disc ratio (C/D) and axial length (AXL).

Inclusion criteria: The study included infants aged below ≤ 1 year with Buphthalmous with or without antiglaucoma medications and not had previous antiglaucoma surgery.

Exclusion criteria: Eyes that had previous antiglaucoma procedure or eyes that need combined operation and infants not fit for GA.

Preoperative examinations

History taking including, age, sex, laterality, antiglaucoma drugs. Ophthalmological examinations were done under GA, includes slit lamp examination, corneal clarity with scoring of corneal cloudiness (0 = no, 1 = mild and 2 = moderate cloudiness), horizontal corneal diameter (HCD), fundus examination and measurement of cup disc ratio, IOP with Perkins tonometer and axial length by ultrasonography. The demographic data were registered as in table 1.

Surgical procedure

All procedures were done by one of the Authors under GA.

In group 1 SST with iris incarceration Steps in brief: Clear corneal traction suture by vicryl 7/0 in the superior peripheral part 1 mm from the limbus. Conjunctival peritomy with fornix based Conjunctival flap was done in the upper temporal quadrant. Half thickness rectangular scleral flab 3.5 x 4.5 mm were constructed. Paracentesis to lower IOP and allows reformation of anterior chamber when needed and check filtration. Block trabeculectomy 1.5 x 2 mm were done manually by knife and vannas scissors. Iris incarceration was done by catching the iris near the pupillary margin and cutting it into 2 pillars, one pillar incarcerated under the scleral flap and the other one reposted with iris repositor resulting in inverted coma shaped pupil. Scleral flap was closed with interrupted 10/0 nylon suture and Conjunctival flap with contentious 10/0 nylon suture then injection of subconjunctival steroid, antibiotic and eye dressing.

In group 2 trabeculotomy Steps in brief: Conjunctival peritomy with fornix based Conjunctival flap was done in the upper temporal quadrant. Superficial rectangular scleral flab 3.5 x 4.5 mm and then small triangular deep scleral flab (modified technique) with deroofing of (SC) anteriorly to the scleral spur and 1 mm in the clear cornea were done. Radial incision into the scleral bed and cutting Schlemm's

canal, exposure of its opening and dilatation of the ostia by trabeculotome. Paracentesis to lower IOP, allows reformation of anterior chamber when needed and to check filtration. Hans trabeculotome was inserted into Schlemm's canal from one side and centripetal rupture of the canal through trabecular meshwork into the anterior chamber about 70 - 90 degree and repeated on the other side. Scleral flap was closed with interrupted 10/0 nylon suture and Conjunctival flap with contentious 10/0 nylon suture then injection of subconjunctival steroid, antibiotic and eye dressing.

Post-operative management

The patients were prescribed topical tobramycin 0.3%- dexamethasone 0.1% (Tobradex, Alcon Co.) eye drops QID and tapering through 4 - 6 weeks, cyclopentolate 0.5% TID, and moxifloxacin 0.5 mg (Vigamox, Alcon Co.) eye drops QID for 2 weeks. Scheduled follow up visits were advised next postoperative day, one week, monthly for three months then each three months for 2 years. Each visit the child subjected to full ophthalmological examinations previously mentioned and antiglaucoma medications were prescribed when needed as if (IOP>18 mmHg) or glaucoma progression, starting by one drug beta blockers and adding dorzolamide or prostaglandin to reach the target IOP. another glaucoma procedure were done if the IOP > 18 mmHg with maximum tolerated medication. Patient's data of the 2 years follow-up were recorded. The results of 1 week, 1, 3 and 6 (months), 1 and 2 (years) were included in the statistical analysis.

Statistical analysis

Data were collected, for statistical analysis done by using SPSS statistical package version 20. Descriptive statistics for the (mean ± SD) were done. Paired student's t-test was used for comparison of two related parameters preoperative and postoperative. For all tests (P value) was considered significant if < 0.05.

Results

Forty eyes with Buphthalmous in 25 child, 15 males and 10 females (15 bilateral and 10 with unilateral Buphthalmous) divided into 2 groups. Group 1 (20 eyes) those underwent Subscleral trabeculectomy (SST) with iris incarceration and group 2 (20 eyes) underwent conventional rigid trabeculotomy through a period of 4 years between January 2015 and February 2019. Table 1 shows patients demographic data in which all eyes in group1 were right eyes and 18 eyes in group 2 were left eyes. Corneal cloudiness was present in 24 eyes (60%) with mean score of 0.68 ± 0.11 and 0.78 ± 0.13 for group1 and group 2. There were no significant difference between both groups regarding the pre-operative (child age at surgery, IOP, HCD, corneal cloudiness, cup disc ratio (C/D) and axial length).

		Groups		
Parameters	**Total**	**SST with iris incarceration**	**Trabeculotomy**	**P value**
Eyes n (%)	40 (100)	20 (50)	20 (50)	0.95
Right n (%)	22 (55)	20 (100)	2 (10)	0.07
Left n (%)	18 (45)	0 (0)	18 (90)	0.08
Laterality n (%)	30 (75)	15 (75)	15 (75)	0.98
Sex (M) n (%)	25 (62.5)	15 (75)	10 (50)	0.02
Age month	6.48 ± 0.85	6.48 ± 84	6.28 ± 0.83	0.9
IOP mmHg	26.40 ± 0.51	26.28 ± 0.73	26.52 ± 0.74	0.92
HCD mm	12.36 ± 0.1	12.32 ± 0.15	12.40 ± 0.16	0.92
Corneal cloudiness (Score, 0 - 2), mean	0.78 ± 0.07	0.68 ± 0.11	0.78 ± 0.13	0.78
Cup/disc	0.56 ± 0.3 (0.3 - 0.8)	0.55 ± 0.28 (0.25 - 0.7)	0.57 ± 0.33 (0.2 - 0.8)	0.66
Axial length, mm	22.70 ± 1.23 (20 - 24)	22.71 ± 1.25 (20 - 24)	22.69 ± 1.24 (20 - 24)	0.88

Table 1: *Patients demographic data mean. SD: Stander Deviation, M: Male, n: Number, %: Percentage and AXL: Axial Length in mm.*

The intraocular pressure mean change overtime were presented in table 2 in which it was reduced from 26.28 ± 0.73 to 13.32 ± 0.94 with 49.3% reduction at 2 years follow up in group 1 compared to its reduction from 26.52 ± 0.74 to 13.90 ± 0.98 at the same time with 47.5% reduction from pre-operative value. Both of groups had significant decrease of the mean IOP all over the follow up visits but it had a tendency to be lower in group 1 with significant difference at 1 week, 1 month and 3 months post-operative visits (p = 0.006, 0.005 and 0.03).

Groups/Time	Pre-operative	1 week	1 month	3 months	6 months	1 year	2 years
SST with iris incarceration Reduction (%)	26.28 ± 0.73	12.56 ± 0.70 -13.72 (52.2)	13.28 ± 0.78 -13.00 (49.5)	13.76 ± 1.04 -12.52 (47.6)	14.88 ± 1.06 -11.40 (43.3)	12.80 ± 0.99 -13.48 (51.3)	13.32 ± 0.94 -12.96 (49.3)
Trabeculotomy Reduction (%)	26.52 ± 0.74	17.28 ± 1.62 -9.24 (34.8)	17.56 ± 1.15 -8.96 (33.8)	17.04 ± 1.17 -9.48 (35.7)	15.36 ± 1.04 -11.16 (42)	14.40 ± 0.99 -12.12 (45.7)	13.90 ± 0.98 -12.62 (47.5)
P value	0.92	0.006	0.005	0.03	0.60	0.50	0.99

Table 2: *Intraocular pressure (mmHg) changes overtime.*

Table 3 demonstrated the number of anti-glaucoma drugs in both groups in which it was reduced comparably throughout the follow up visits with significant differences at 1 week and 1 month visits (p = 0.04 and 0.05).

Groups/Time	Pre-operative	1 week	1 month	3 months	6 months	1 year	2 years
SST with iris incarceration	0.56 ± 0.13	0.0	0.28 ± 0.7	0.36 ± 0.8	0.4 ± 0.66	0.25 ± 0.50	0.26 ± 0.54
Trabeculotomy	0.60 ± 0.14	0.28 ± 0.62	0.56 ± 0.5	0.40 ± 0.7	0.36 ± 0.64	0.30 ± 0.79	0.33 ± 0.88
P value	0.68	0.04	0.05	0.3	0.6	0.5	0.6

Table 3: *Number of anti-glaucoma medications.*

Regarding to the success rate as shown in table 4 it was noticed that complete and qualified success rates were superior in group 1 than group 2 all over the follow up visits till it reached to 100% versus (40 and 50%) at 2 years with highly significant differences (p = 0.004 and 0.005). At 2 years follow up, failure rate was (0%, no failed eye) versus (50%, 10 eyes) for group 1 versus group 2 with very high significant difference (p = 0.0001). The 10 failed eyes (50%) in group 2 were due to high IOP 25.3 ± 0.99 and disease progression in spite of maximum tolerated medication, those eyes underwent a second surgical interference at mean time of 8.5 ± 1.5, range (4 - 12 months) from the first procedure in the form of repeated trabeculotomy 180 degree away from the previous one in 8 eyes and trabeculectomy with Mitomycin c (MMC) 0.02% (0.2 mg/ml) for 2 minutes exposure in 2 eyes. Out of the 8 eyes underwent repeated trabeculotomy 6 eyes (75%) had complete success at 14.8 ± 3.6 follow up months and the other 2 eyes (25%) did trabeculectomy with MMC with the previous concentration at 9-12 months. The number of another surgical intervention was highly statistical significant different (p = 0.0001).

	Complete		Qualified		Failure	
	Group 1 N = 20	Group 2 N = 20	Group 1 N = 20	Group 2 N = 20	Group 1 N = 20	Group 2 N = 20
1 week n (%)	19 (95)	18 (90)	20 (100)	20 (100)	0	0
3 months n (%)	18 (90)	14 (70)	20 (100)	16 (80)	0	4 (20)
6 months n (%)	19 (95)	10 (50)	20 (100)	12 (60)	0	8 (40)
1 year n (%)	18 (90)	9 (45)	20 (100)	10 (50)	0	10 (50)
2 years n (%)	20 (100)	8 (40)	20 (100)	10 (50)	0	10 (50)
P value	0.004		0.005			0.0001

Table 4: *Success and failure rate over time.*

Table 5 showing the mean change in HCD and C/D ratio overtime in which the mean preoperative HCD reduced from 12.52 ± 0.15 mm to 11.60 ± 0.095 and from 12.50 ± 0.16 to 11.66 ± 0.097 at 2 years with 0.92 mm (7.3%) and 0.84 mm (6.72%) reduction for group 1 versus group 2 and there was no statistically significant difference between them at all visits *(*P > 0.05*).* Regarding the mean vertical C/D ratio it was reduced from 0.55 ± 0.28 to 0.45 ± 0.40 and from 0.57 ± 0.33 to 0.48 ± 0.40 with 0.1 mm (18%) and 0.09 mm (15.8%) reduction for group 1 versus group 2 from the pre-operative value at 2 years visit with no statistically significant difference between groups at all visits in spite of better results for group 1 *(*P > 0.05*).*

Items	Groups / Time	Preoperative	1 week	1 month	3 months	6 months	1 year	2 years
Corneal diameter	SST with iris incarceration	12.52 ± 0.15	12.24 ± 0.15	12.24 ± 0.15	11.94 ± 0.13	11.64 ± 0.12	11.62 ± 0.095	11.60 ± 0.095
	Trabeculotomy	12.50 ± 0.16	12.32 ± 0.15	12.32 ± 0.15	11.95 ± 0.15	11.66 ± 0.13	11.76 ± 0.11	11.66 ± 0.097
	P value	0.92	0.88	0.88	0.63	0.77	0.88	0.88
Cup / disc	SST with iris incarceration	0.55 ± 0.28	0.55 ± 0.38	0.54 ± 0.30	0.50 ± 0.36	0.41 ± 0.26	0.40 ± 0.38	0.45 ± 0.40
	Trabeculotomy	0.57 ± 0.33	0.56 ± 0.40	0.55 ± 0.45	0.53 ± 0.38	0.45 ± 0.34	0.43 ± 0.36	0.48 ± 0.40
	P value	0.66	0.78	0.88	0.62	0.67	0.98	0.88

Table 5: *Corneal diameter (mm) and Cup disc ratio change over time.*

Table 6 showing the mean change in axial length (AXL) overtime in which the mean AXL was decreased from 22.71 ± 1.25 to 21.81 ± 1.65 and from 22.69 ± 1.28 to 21.82 ± 1.75 at 2 years with 0.90 mm (3.9%) and 0.87 mm (3.8%) reduction for group 1 versus group 2 and there was no statistically significant difference between groups at all visits in spite of better results for group 1 (P > 0.05).

Items	Groups/Time	Preoperative	1 week	1 month	3 months	6 months	1 year	2 years
Axial length	SST with iris incarceration Difference	22.71 ± 1.25	21.56 ± 1.55 1.15	21.77 ± 1.45 0.94	21.83 ± 1.35 0.88	21.91 ± 1.25 0.80	21.82 ± 1.50 0.89	21.81 ± 1.65 0.90
	Trabeculotomy	22.69 ± 1.28	21.66 ± 1.65	21.79 ± 1.55	21.85 ± 1.34	21.93 ± 1.27	21.84 ± 1.52	21.82 ± 1.75
	Difference		1.03	0.90	0.84	0.76	0.85	0.87

Table 6: *Axial length changes over time.*

There were minimal intra-operative complications in the form of mild hyphema in 12 eyes (60%) in group 2 versus nothing in group 1 and in all eyes it resolved gradually on the first post-operative days. Post-operative minor complications were present in one eye in group 1 in which the iris pillar creeping up under the scleral flap drawing up the pupil noticed at 9 months postoperatively and was managed by lower pupillary sphincterotomy through Paracentesis. Shallow anterior chamber was found in 4 eyes (20%) in group 1. Mild hyphema was present in 6 eyes (30%) and shallow anterior chamber in 3 eyes (15%) in group 2. These minor complications were resolved with close observation as well as there were no major postoperative ocular complications such as endophthalmitis, secondary cataract formation and retinal detachment.

Discussion

Subscleral trabeculectomy (SST) lowers IOP by creating a fistula that allow aqueous filtration from anterior chamber to subconjunctival space, soon or later this filtration would be altered due to excessive scaring, fibrosis and adhesions between the scleral flap and its

bed especially in this very young age and the IOP rise again and so called failed trabeculectomy. So, trabeculectomy modifications are continuously needed. In 1979, Kottow [10] described a modification called scleral wick in which the trabeculectomy tissue is not completely excised but hinged diagonally and sutured across the scleral bed acting as a wick in his series most of patients were adults with different glaucoma types. Another modification such as synthetic, foreign materials or collagen implant was used under the scleral flap with its disadvantages of infection and rejection [11,12]. As well as the use of antimetabolites such as Mitomycin C and 5-Fluorouracil to guard against scaring and fibrosis with its complications [3,13,14]. In 1974, El-Shewy [15] described another technique called Subscleral iridencleisis in which he did deep scleral incision under the Conjunctival and Scleral flap then he incarcerate one iris pillar in this wound without trabeculectomy for adult patients with open angle glaucoma. Iris inclusion Perce as anti-glaucoma procedure is obsolete 3 decades ago for the reason of many complications such as infection and disfigurement.

From embryological background the iris is derived from neuroectodermal epithelium and the sclera from extracellular mesenchyme and hence little chance for adhesion between them. In our study we used a technique for modification of SST in management of Buphthalmous in infants that we termed it (SST with iris incarceration) in which we used one iris pillar incarcerated in the sclerostomy or the Subscleral window after excision of the trabecular block and under the scleral flap to decrease the opposition of the flap and its bed as well as to act as a wick facilitating filtration and decreasing the incidence of scaring with minimal complications and slight disfiguring of the pupil shape as all pupils becomes inverted coma shaped but with excellent and encouraging results and by following of some of our patients around six years old now this disfigurement does not affect the vision much. In reviewing the literatures and to the best of our knowledge no body used such our modification technique to SST. Our study documented that all over the 2 years follow up the eyes that underwent SST with iris inclusion had lower IOP and needed fewer number of anti-glaucoma drugs than the eyes that did conventional trabeculotomy. This difference was statistically significant at 1week,1 month and 3 months for IOP (p = 0.006, 0.005 and 0.03) and at 1week and 1 month for the number of anti-glaucoma drugs (p = 0.04 and 0.05). Our results in reduction of IOP at 2 years follow up either in group 1 (49.3%) or group 2 (47.5%) are comparable to that of Temkar., *et al*. 2015 [16] in which their IOP reduction was 46.92% to their microcatheter group and 46.61% to their trabeculotomy- trabeculectomy group in PCG.

The success rate for either the complete or qualified success was 100% in SST with iris incarceration group versus 40% and 50% in trabeculotomy group with highly statistically significant difference (p = 0.004 and 0.005) as well as no one eye failed in group1 and required another antiglaucoma procedure compared to 10 eyes (50%) in group 2 with highly statistically significant difference (p = 0.0001). Those 10 eyes required second intervention and 2 eyes (10%) required third intervention with more exposure to anesthesia as well as patient and eye burden. Our success rate in SST with iris incarceration (group 1) was superior to many antiglaucoma procedures studies such as Neustein and Beck, 2017 [17] in which their success rate was 81% for microcatheter group and 31% for conventional trabeculotomy group in PCG. Our success rate in group 1 higher than that of Elsayed and Jawdat, 2017 [18] group 1 that underwent microcatheter trabeculotomy with complete success rate of 67% and qualified success rate of 85% as well as superior in failed rate as it was zero for us and 15% for them, but our success rate in group 2 was comparable to their success rate in rigid trabeculotomy group in which it was 47% for complete success and 50% for qualified success. Also our complete success rate for group 1 higher than the complete success rate of Toshev., *et al.* 2018 [9] in which their complete success rate was 80% and comparable in our qualified success to their qualified success of 100% for microcatheter group. Our success rate for group 2 were comparable to that of Elsheikha., *et al*. 2015 [19] in which their success rate was 60% for trabeculotomy and comparable with Shi., *et al.* 2016 [8] in which their complete success was 51.6% and qualified success was 61.9% for trabeculotomy.

Regarding to the mean change in HCD in our study it was reduced at 2 years by 0.92 mm (7.3%) and 0.84 mm (6.72%) from preoperative values for group 1 versus group 2 and regarding the mean vertical C/D ratio it was reduced by 0.1 mm (18%) and 0.09 mm (15.8%) for group 1 versus group 2 from the pre-operative value at 2 years visit and this finding was comparable with that of Dada., *et al.* 2014 [2] in which they reported 17.5% reduction in cup disc ratio at 12 month follow up using microcatheter in PCG management. The previous findings demonstrated the efficacy of our procedure SST with iris incarceration in prevention of glaucoma progression with low coast as an economical issue in our developing country compared to using a microcatheter which has a high coast. As well as the mean AXL in

our study was decreased at 2 years with 0.90 mm (3.9%) and 0.87 mm (3.8%) reduction for group 1 versus group 2 and these results are comparable with Kook., *et al.* 2001 [13] in which they reported a decrease of AXL by 0.91 mm at 12 months in their study of augmented trabeculectomy with MMC in primary open angle glaucoma whoever, the age group (mean age was 45.7 years) and disease entity are different than that of our study.

Conclusion

SST with iris incarceration was superior in controlling the IOP with first surgical interference with less complications and good visual function in comparison to trabeculotomy in which the eyes needed more surgical interventions. SST with iris incarceration is a safe surgical procedure and yielded good IOP control and excellent success rate should encourage its widespread use in Buphthalmous.

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Conflicts of Interest

The authors declare that they didn't have either conflicts of interests or financial interests; in addition, these data have not been published before.

Declarations

Ethics Approval and Consent to Participate

The study was approved by the local ethical board committee. Before the procedure, each patient parent was adequately informed about the study as well as the risks and benefits of the procedure, and signed informed consent in accordance with the Declaration of Helsinki.

Consent for Publication

Not applicable.

Availability of Data and Material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Funding

Not applicable.

Authors' Contributions

Conduct of the study, preparation, design, and critical revision (E SH & E A); supervision; data collection, statistical analysis, writing, drafting of manuscript and editing the paper (E SH) and material support, follow up and review (E A and E SH).

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