Acta Ophthalmologica

Acta Ophthalmologica 2016

Primary trabeculotomy compared to combined trabeculectomy–trabeculotomy in congenital glaucoma: 3-year study

Dalia H. Khalil and Mohamad A. S. E. Abdelhakim

Department of Ophthalmology, Kasr Al-Ainy Hospital, Cairo University, Cairo, Egypt

ABSTRACT.

Purpose: **To compare the outcome of primary trabeculotomy with that of combined trabeculectomy–trabeculotomy (CTT) with mitomycin C (MMC) in children with congenital glaucoma.**

Methods: **This is a prospective comparative study, carried out on a cohort of 28 eyes (28 infants) with congenital glaucoma. Infants with proved congenital glaucoma [based on intra-ocular pressure (IOP), cup/disc (C/D ratio), corneal diameter and axial length measurements] were randomly allocated to either group A (trabeculotomy) or group B (CTT with MMC). Postoperatively, all patients were followed regularly for 3 years; for IOP and C/D evaluation. Criteria for successful outcome included resolution of corneal oedema, reversal of disc cupping, and IOP 18 mmHg or less.**

Results: **Success rate in each group was 85.7% (p = 1.00). All preoperative parameters, including horizontal corneal diameter, axial length, IOP and C/D ratio, were not statistically significantly different between the two groups. Also, postoperative C/D ratio, IOP, IOP difference and percentage difference (compared to preoperative values), at different follow-up visits, were not statistically significantly different between both surgical techniques. Comparing preoperative to postoperative IOP and C/D ratio in each group was statistically significant.**

Conclusion: **Both primary trabeculotomy and CTT with MMC had similar outcomes, which could mean that trabeculotomy could be resorted to first.**

Key words: combined trabeculotomy–trabeculectomy – congenital glaucoma – success rate – trabeculotomy

Acta Ophthalmol. 2016: 94: e550–e554

doi: 10.1111/aos.13018

Introduction

Surgical intervention is the main treatment for congenital glaucoma as it eliminates the resistance to aqueous outflow created by structural abnormalities in the anterior chamber angle (Papadopoulos & Khaw 2007). Goniotomy and trabeculotomy have traditionally been considered as procedures of choice because of high reported success rates. Goniotomy has the advantage of preserving the conjunctiva for future use, while trabeculotomy has the advantage of being possible in eyes with improper visualization (McPherson & Berry 1983).

Combined trabeculotomy–trabeculectomy (CTT) has been found to yield superior results in comparison with conventional procedures (Elder 1994), yet there has been no study directly comparing the results of trabeculotomy with CTT for congenital glaucoma. So, the aim of this work was to compare the outcome of primary trabeculotomy with that of CTT with mitomycin C.

Patients and Methods

This is a prospective comparative study, carried out on a cohort of 28 eyes of 28 Egyptian infants diagnosed with primary congenital glaucoma (PCG). The study was performed during the time period between January 2012 and September 2012. Patients were selected from the Kasr Al-Ainy Cairo University Hospitals Aboul Riech Pediatric outpatient clinic. Kasr Al-Ainy hospital is a Central University Hospital in Cairo, and it is a tertiary referral centre for most of the governorates in Egypt. Approval for the study was obtained from the Ophthalmology Department Ethical Committee (according to the WMA Declaration of Helsinki). All infants' guardians received a thorough explanation of the study design and aims and were provided with written informed consent.

Inclusion criteria were patients presenting with PCG in the first 2 years of life with no previous ocular surgeries. Any childhood glaucoma other than PCG was excluded, and only primary surgical cases were evaluated.

Each patient's age, sex, family history and consanguinity history was noted, and each underwent a careful

ocular examination under general anaesthetic (halothane, nitrous oxide and oxygen). Examination included measuring horizontal corneal diameters with callipers, documenting the presence or absence of corneal oedema and Haab striae, measuring intra-ocular pressure (IOP) with Perkins hand held applanation tonometer and optic disc evaluation by direct and indirect ophthalmoscopy to determine the presence or absence of cupping (a cup–disc ratio of 0.3 or higher was considered suspicious). If a cloudy cornea was restricting examination, topical glycerine solution was instilled to improve the view. B-scan ultrasound was used to measure the cupping when attempts to improve the view were not successful. Axial length was also recorded using biometry.

Infants with proved congenital glaucoma were randomly (using random computer-generated numbers) allocated to either group A (trabeculotomy) or group B (combined trabeculotomy–trabeculectomy with mitomycin C) under general anaesthesia.

Surgical technique

Trabeculotomy

A limbus-based conjunctival flap and Tenon's capsule (without excision) were raised. A superficial scleral flap, measuring 4 × 5 mm, was raised at 12 o'clock. The access to Schlemm's canal was made via a radial incision 1 mm inside the margin of the scleral flap that was gradually deepened until the canal was visible. This was often confirmed by the drainage of aqueous and the appearance of the glistening, longitudinal striations of the inner aspect of the canal. The canal was cannulated with a Harms trabeculotome that was then rotated into the anterior chamber to cleave the trabecular meshwork. The canal was cannulated in both directions; this provided approximately 140° of angle cleavage. Finally, the superficial scleral flap was sutured to the globe with two interrupted 8/0 vicryl sutures, and the conjunctiva was closed with interrupted sutures of 8/0 vicryl.

Combined trabeculotomy–trabeculectomy

After dissection of the superficial scleral flap, MMC (0.2 mg/ml) soaked pieces of microsponge 4 × 4 mm^2 were applied under the scleral flap and the conjunctiva for 4 minutes, and then washed with copious saline. Then trabeculotomy was performed as described above, followed by removal of a block of scleral tissue measuring approximately 1 × 3 mm. This included Schlemm's canal as for a routine trabeculectomy. A peripheral iridectomy was performed. Finally, the superficial scleral flap and the conjunctiva were closed.

Three eyes, in which Schlemm's canal could not be identified easily intra-operatively, were operated for trabeculectomy and excluded from the study. All the patients were followed regularly at 1 month, 6 months, 1–3 years. Postoperative follow-up was based on serial examinations under anaesthetic measuring IOP and optic disc evaluation. Intra-operative and postoperative complications were recorded.

Criteria for successful outcome included resolution of corneal oedema, reversal of disc cupping, and an IOP measurement of 18 mmHg or less on no IOP-lowering medical treatment.

Data were statistically described in terms of range, mean ± standard deviation (± SD), median frequencies (number of cases) and percentages when appropriate. Comparison of numeric variables between groups was performed using the unpaired Student's *t*-test, while within-group comparison was performed using paired Student's *t*-test. For comparing non-parametric data, Mann–Whitney and Wilcoxon tests were performed whenever appropriate. Chi-square (χ^2) test was performed for comparing categorical data. All p values less than 0.05 was considered statistically significant. All statistical calculations were carried out using computer program's MICROSOFT EXCEL 2007 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 18 for the Microsoft Windows. Due to lack of any reports for the incidence rate of PCG for the Egyptian population, sample size was calculated using MEDCALC 10.2.0.0 (MedCalc Software bvba, Ostend, Belgium), by referring to success rates of trabeculotomy and combined trabeculectomy–trabeculotomy from literature.

Results

Fourteen infants were allocated to each group. The infants' demographic data including age at the time of diagnosis and gender are shown in Table 1. There was no significant difference between both groups regarding age and gender (p = 0.549 and p = 1.00, respectively).

All preoperative data at the time of diagnosis including number of opaque corneas, the horizontal corneal diameter, the axial length, cup/disc (C/D) ratio and intra-ocular pressure (IOP) are also shown in Table 1. There was also no significant difference between both groups regarding these data (p = o.663, p = 0.669, p = 0.164, p = 0.886, p = 0.918, respectively).

All postoperative data including C/D ratio, IOP changes and number of clear

Table 1. Demographic and preoperative data in group A (Trabeculotomy) and group B [Combined trabeculotomy–trabeculectomy (CTT) with mitomycin C (MMC)].

	Group A (Trabeculotomy)	Group B (CTT + MMC)	p value
Age in months [mean ± SD (range)]	6.52 ± 3.89 (1.3–18)	5.62 ± 3.96 (1–17)	0.549
Gender (Boys) [no. (%)]	11 (78.57%)	11 (78.57%)	1.00
Opaque corneas [no. (%)]	10 (71.43%)	11 (78.57%)	0.663
Horizontal corneal diameter in mm [mean ± SD (range)]	13.46 ± 1.15 (11–15)	13.29 ± 1.03 (11–15)	0.669
C/D ratio [mean ± SD (range)]	0.64 ± 0.14 (0.4–0.9)	0.63 ± 0.11 (0.5–0.9)	0.886
IOP in mmHg [mean ± SD (range)]	24.14 ± 1.88 (22–28)	24.07 ± 1.77 (22–28)	0.918
Axial length in mm [mean ± SD (range)]	23.17 ± 1.76 (18.9–26.5)	22.28 ± 1.55 (19.2–24.4)	0.164

p values < 0.05 are considered statistically significant.

corneas are shown in Table 2. Postoperative IOP and percentage drop in IOP at each follow-up visit, C/D ratio and clear corneas were not significantly different between both groups. Postoperative IOP behaviour throughout the follow-up period in both groups is shown in Fig. 1. Comparing preoperative IOP to postoperative IOP at each follow-up period in each group was statistically significant ($p < 0.001$ for each). Also comparing preoperative to postoperative C/D ratio in each group was statistically significant ($p < 0.001$).

Success rate in each group was 85.7%; that is, 85.7% of the eyes had IOP less than 18 mmHg on no medication ($p = 1.00$). At 6 months postoperatively, two eyes in each group had IOP > 18 mmHg on medical treatment. In group A, the two eyes were controlled with trabeculectomy with MMC, and those in group B were reoperated for trabeculectomy with MMC. These four eyes maintained IOP < 18 mmHg on no medication thereafter.

Hyphaema occurred in five eyes (35.7%) in group A and four eyes (28.6%) in group B due to cleavage of angle vessels. It resolved 3 days postoperatively. There was one eye (7.1%) with moderate anterior chamber reaction in group A which resolved with medical treatment for 10 days. Comparing complication rate between both groups was statistically insignificant ($p = 0.430$). There were no other perior postoperative complications in either group.

Discussion

Prospective comparative studies are scarce in this field because of the infrequent and variable prevalence of this condition in different areas of the world. To our best knowledge, this was the first prospective study to compare primary trabeculotomy with combined trabeculotomy–trabeculectomy (CTT) with mitomycin C (MMC) in cases of PCG.

In this work, 14 eyes were allocated to each group. The infants' mean age at the time of diagnosis was 6.52 years of age in the trabeculotomy group and 5.62 years of age in the CTT group, with 11 boys in each group. Age and sex were not statistically significantly different between both groups, so they were almost age and sex matched.

Also all the preoperative parameters, including horizontal corneal diameter (HCD), axial length, intra-ocular pressure (IOP) and cup/disc (C/D) ratio, were not statistically significantly different between the two groups. In the trabeculotomy group, the mean preoperative HCD was 13.46 ± 1.15 mm, while it was 13.29 ± 1.03 mm in the CTT group. In the study conducted by Debnath et al. (1989) comparing trabeculectomy with trabeculotomy, the HCD in some eyes was > 14 mm in each group.

In our work, the mean preoperative IOP in the trabeculotomy group was 24.14 ± 1.88 mmHg, and 24.07 ± 1.77 mmHg in the CTT group, while in the study by Debnath and colleagues (1989) some eyes had IOP > 35 mmHg, and in the study by Elder (1994) which compared CTT with trabeculectomy, IOP was 28.4 mmHg in the trabeculectomy group and 32.6 mmHg in the CTT group. In a study by Zetterberg et al. (2015), describing a paediatric cohort surgically treated for primary or secondary glaucoma (PG/SG), the mean preoperative IOP was 31.5 mmHg.

Regarding other preoperative parameters, our mean preoperative C/D ratio was 0.64 ± 0.14 in the trabeculotomy group with mean axial length 23.17 ± 1.76 mm while it was

Table 2. Postoperative cup/disc (C/D) ratio, intra-ocular pressure (IOP) changes and number of clear corneas in group A (Trabeculotomy) and group B [Combined trabeculotomy–trabeculectomy (CTT) with mitomycin C (MMC)].

			Group A (trabeculotomy)	Group B (CTT + MMC)	p value
C/D Ratio [mean ± SD (range)]		Value	0.43 ± 0.18 (0.2–0.7)	0.44 ± 0.17 (0.2–0.7)	0.827
		Difference from preoperative	0.21 ± 0.12 (0–0.4)	0.19 ± 0.12 (0–0.4)	0.637
		% difference	33.51 ± 18.62 (0–60)	30.53 ± 19.07 (0–60)	0.680
IOP [mean ± SD (range)]	1 month	Value (mmHg)	11.07 ± 1.94 (8–14)	11.29 ± 2.02 (8–14)	0.777
		Difference from preoperative (mmHg)	13.07 ± 3.08 (8–18)	12.79 ± 2.67 (8–17)	0.795
		% difference	53.72 ± 10.05 (36.36–64.29)	52.89 ± 9.27 (36.36–68)	0.821
	6 months	Value (mmHg)	11.43 ± 4.86 (8–22)	12.43 ± 5.09 (8–24)	0.600
		Difference from preoperative (mmHg)	12.71 ± 3.91 (4–17)	11.64 ± 3.99 (2–15)	0.480
		% difference	53.28 ± 16.86 (15.38–68)	49.10 ± 17.17 (7.69–63.64)	0.521
	1 year	Value (mmHg)	10.00 ± 1.75 (8–14)	10.43 ± 1.79 (8–14)	0.527
		Difference from preoperative (mmHg)	14.14 ± 1.88 (12–17)	13.64 ± 1.55 (12–17)	0.449
		% difference	58.59 ± 6.33 (46.15–68)	56.76 ± 5.73 (46.15–68)	0.431
	2 years	Value (mmHg)	9.86 ± 1.83 (8–14)	10.57 ± 2.14 (8–14)	0.351
		Difference from preoperative (mmHg)	14.29 ± 1.77 (12–17)	13.50 ± 1.79 (10–17)	0.253
		% difference	59.23 ± 6.35 (46.15–68)	56.21 ± 7.27 (41.67–68)	0.251
	3 years	Value (mmHg)	10.00 ± 2.08 (8-14)	10.71 ± 2.02 (8–14)	0.364
		Difference from preoperative (mmHg)	14.14 ± 2.90 (12–17)	13.36 ± 1.65 (10–17)	0.226
		% difference	58.72 ± 6.80 (46.15–68)	55.61 ± 6.66 (41.67–68)	0.232
	Clear corneas [no. (%)]		13 (92.86%)	12 (85.71%)	0.541

p value < 0.05 is considered statistically significant.

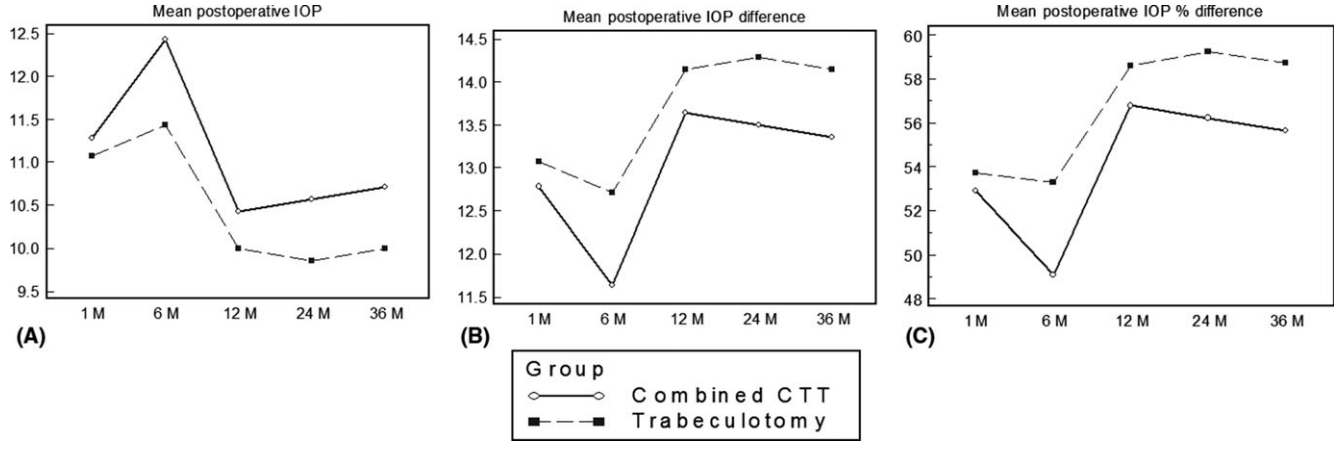

Fig. 1. Postoperative intra-ocular pressure (IOP) behaviour during the follow-up period in both groups. (A) Mean postoperative IOP values, (B) Mean postoperative IOP difference from preoperative values, (C) Mean postoperative IOP percentage difference from preoperative values.

0.63 ± 0.11 in the CTT group with mean axial length 22.28 ± 1.55 mm. Of the 14 eyes in each group, 71.43% in the trabeculotomy group and 78.57% in the CTT group had opaque cornea preoperatively. In the study by Elder (1994), 82% in the trabeculectomy group and 56% in the CTT group had preoperative corneal haze.

Viscotrabeculotomy has also been described for surgical treatment of congenital glaucoma. In a comparative study by ElSheikha et al. (2015), they assessed the efficacy of viscotrabeculotomy in the management of congenital glaucoma as compared to conventional trabeculotomy, in Egyptian infants. The mean preoperative IOP was 24.3 mmHg in trabeculotomy group with HCD 13.3 mm and 22.2 mm axial length while it was 23.5 mmHg in the viscotrabeculotomy group with HCD 13.5 mm and 22.8 mm axial length.

Trabeculotomy removes the possible obstruction to aqueous outflow, creating a direct continuity between the anterior chamber and Schlemm's canal. Also in advanced buphthalmos, it is easier to convert to trabeculectomy in cases where identification of Schlemm's canal is not possible (Elder 1994).

We followed the 28 eyes for 3 years following surgery. In our work, postoperative C/D ratio, IOP, IOP difference and percentage difference (compared to preoperative values), at different follow-up visits, were not statistically significantly different between both surgical techniques. We reported these values at 1 and 6 months, and 1-, 2- and 3-year periods. The IOP and the percentage drop in IOP at these different periods are shown in Table 2 with mean IOP at the last visit 10 mmHg (58.72% drop) in the trabeculotomy group and 10.71 mmHg (55.61% drop) in the CTT group. In the study by Elder (1994), the mean postoperative IOP was reported at the last follow-up visit to be 14.4 mmHg for the CTT group, while in the study by Zetterberg and colleagues (2015) it was 17.1 mmHg. In most of these studies, the percentage drop in IOP was not reported.

In the study by ElSheikha et al. (2015), the follow-up was at 1 day, 1 week, weekly for 1 month and then monthly for 6 months. Postoperatively, IOP dropped at 6 months to 14.7 mmHg and 17 mmHg in the viscotrabeculotomy and trabeculotomy groups, respectively. That was significant in either group when compared to preoperative IOP, but not significant between both groups at the same point of comparison.

Postoperatively, success rate in each group was 85.7%; that is, 85.7% of the eyes had IOP less than 18 mmHg on no medication, with no statistical significant difference between both groups. Preoperative IOP compared to postoperative IOP was statistically significant in each group at each follow-up period. We had four eyes with IOP > 18 mmHg on medical treatment at 6 months postoperatively. They were all operated for trabeculectomy with MMC and the IOP stayed < 18 mmHg till the end of the 3 year follow-up. Other studies in India and the Middle East, where CTT is commonly used, reported surgical success rates ranging between 75 and 94%. Many of these studies however involved larger numbers, long FUP periods and differences in definition of surgical success, which may explain the wide range of success (Mandal et al. 2003; Al-Hazmi et al. 2005.)

In the study by Debnath and colleagues (1989), the success rate of trabeculectomy and trabeculotomy procedures were very close, but they still recommended trabeculotomy as an initial primary procedure because trabeculectomy carries a higher rate of complications.

The study of Elder (1994) proved that primary trabeculectomy for congenital glaucoma gives adequate long-term success with few complications, while the combined procedure may have a higher success rate, and this requires further investigation. But goniotomy and trabeculotomy remain the standards in congenital glaucoma as both procedures are successful and have been assessed over a long period of time.

In the study by ElSheikha et al. (2015), complete success was achieved in 61.9% (13 eyes) of the viscotrabeculotomy group compared to 60.0% of the trabeculotomy group (12 eyes). Qualified success was recorded for one eye (4.8%) in the viscotrabeculotomy group compared to none in trabeculotomy group. Failure was encountered in seven eyes (33.3%) of the viscotrabeculotomy group and eight eyes (40%) of the trabeculotomy group. The differences of complete success and failure between either group were not statistically significant.

In another study in South Korea, 50.64% of the eyes received one operation and 45.2% received more than

two operations. Qualified success rate defined as a final IOP <21 mmHg with or without antiglaucoma medications was 70.6% and 61.8% at postoperative 1 and 5 years, respectively (Suh & Kee 2015).

In our work, 92.86% of the eyes in the trabeculotomy group and 85.71% in the CTT group had clear cornea postoperatively. In the study by ElSheikha et al. (2015), 25% in the trabeculotomy group and 14.3% in the viscotrabeculotomy group had clear cornea through the follow-up period, 8.3% and 7.1% in each group, respectively, with hazy corneal opacity and the rest showing Haab's striae.

Complication rate in our study was 6/14 eyes in the trabeculotomy group and 4/14 in the CTT group. In the trabeculotomy group, we had five eyes with postoperative hyphaema and one eye with moderate anterior chamber reaction, which all resolved without any residual effects. In the CTT group, there were four eyes with self-limited hyphaema. Apart from these complications, we did not notice any other intra- or postoperative complications.

In the study by Debnath et al. (1989), serious complications such as loss of vitreous, endophthalmitis and shallow anterior chamber occurred with trabeculectomy. Hyphaema was more common with trabeculotomy, but was benign and caused no additional problems.

Elder (1994) reported hyphaema in 4/16 eyes with no other perioperative or postoperative complications, in the CTT group. While in the trabeculectomy group he reported hyphaema in 4/44 eyes, otherwise there were no perioperative or early postoperative complications. There was no vitreous loss. Iridotrabeculodysgenesis was described in 3/44 patients, while the rest had presumed isolated trabeculodysgenesis. Late complications included one retinal detachment, one subluxed lens and three cataracts that required lensectomy.

As a conclusion, in our work both primary trabeculotomy and CTT with MMC had similar success rates and postoperative parameters, which could mean that trabeculotomy could be resorted to first, saving trabeculectomy for future intervention. The limitation in our study was the small number of eyes studied, which could be expanded in future studies.

References

Al-Hazmi A, Awad A, Zwaan J, Al-Mesfer AS, Al-Jadaan I & Al-Mohammed A (2005): Correlation between surgical success rate and severity of congenital glaucoma. Br J Ophthalmol **89**: 449–453.

Debnath SC, Teichmann KD & Salamah K (1989): Trabeculectomy versus trabeculotomy in congenital glaucoma. Br J Ophthalmol **73**: 608–611.

Elder MJ (1994): Combined trabeculotomy–trabeculectomy compared with primary trabeculectomy for congenital glaucoma. Br J Ophthalmol **78**: 745–748.

ElSheikha OZ, Abdelhakim MA, Elhilali HM & Kassem RR (2015): Is viscotrabeculotomy superior to conventional trabeculotomy in the management of Egyptian infants with congenital glaucoma? Acta Ophthalmol **93**: e366–e371.

Mandal AK, Gothwal V, Bagga H, Nutheti R & Mansoori T (2003): Outcome of surgery on infants younger than 1 month with congenital glaucoma. Ophthalmology **110**: 1909–1915.

McPherson SD Jr & Berry DP (1983): Goniotomy vs external trabeculotomy for developmental glaucoma. Am J Ophthalmol **95**: 427–431.

Papadopoulos M & Khaw PT (2007): Advances in the management of paediatric glaucoma. Eye (Lond) **21**: 1319–1325.

Suh W & Kee C (2015): Long-term outcome of primary congenital glaucoma in South Korea. Acta Ophthalmol. **94**: 162–163.

Zetterberg M, Nyström A, Kalaboukhova L & Magnusson G (2015): Outcome of surgical treatment of primary and secondary glaucoma in young children. Acta Ophthalmol **93**: 269–275.

Received on October 3rd, 2015.
Accepted on January 22nd, 2016.

Correspondence:
Mohamad A. S. E. Abdelhakim, MD
11c, Street 199, Apt. # 9
Degla, Maadi
Cairo 11431
Egypt
Tel: 00201002592639
Fax: 25165690
Email: m.amr.salah@kasalainy.edu.reg

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Contributionship: Dalia H. Khalil: Collection of data; Conduction of study; Analysis and interpretation of data; Drafting the work. Mohamad AS Abdelhakim: Collection of data; Conduction of study; Analysis and interpretation of data; Drafting the work.