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# Hysteroscopic versus laparoscopic management in patients with communicating hydrosalpinx and planning for IVF: a randomized controlled trial

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## Abstract

**Background:** Hydrosalpinx is considered one of the obstacles that could hinder the success of IVF techniques due to the toxic effect of the hydrosalpinx fluid pouring into the uterine cavity. Tubal disconnection by either hysteroscopic or laparoscopic approaches is considered the standard in the operative management of hydrosalpinx prior to IVF cycles. The aim of the current study was to compare the success rate of hysteroscopic tubal occlusion using electro-coagulation with laparoscopic tubal disconnection in cases of hydrosalpinx prior to in vitro fertilization (IVF).

**Methods:** A total of 108 women with unilateral or bilateral hydrosalpinx, who were candidates for tubal occlusion before IVF, were equally randomized into two groups. Group A ( $n = 54$ ) underwent hysteroscopic tubal occlusion using the roller-ball electro-coagulation of the interstitial part of the tube and the uterine cornual area, and group B ( $n = 54$ ) underwent laparoscopic tubal disconnection using bipolar coagulation and a proximal tubal cut. Operative time, complications, postoperative pain measured by the visual analogue score (VAS score), and postoperative hospital stay were recorded for both groups. The success rate of tubal occlusion was assessed 1 month later using a post-menstrual hysterosalpingogram (HSG).

**Results:** Laparoscopic tubal disconnection was more successful than the hysteroscopic approach regarding tubal occlusion rate (96.15% vs. 86.67% respectively,  $p = 0.044$ ). The operative time and postoperative pain VAS scores in the hysteroscopy group ( $3.65 \pm 1.03$  min and  $1.81 \pm 1.35$ , respectively) were significantly lower than that in the laparoscopy group ( $17.48 \pm 4.70$  min and  $4.06 \pm 1.65$ , respectively) with  $p < 0.001$ .

**Conclusion:** Although laparoscopic tubal disconnection is more successful, the hysteroscopic approach is an alternative which has its own limitations that can be assessed by hysterosalpingogram, especially when laparoscopy is contraindicated, technically difficult, or refused by the patient.

**Trial registration:** It was first registered at ClinicalTrials.gov on 30/07/2019 with registration number [NCT04037813](https://clinicaltrials.gov/ct2/show/study/NCT04037813).

**Keywords:** Hydrosalpinx, Hysteroscopy, Infertility, IVF, Laparoscopy

## Background

Hydrosalpinx is considered a poor prognostic factor regarding successful fertilization rates in in vitro fertilization (IVF) cycles [1]. Its prevalence in IVF patients ranges from 10 to 13% using ultrasound and may reach

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up to 30% when diagnosed by hysterosalpingogram (HSG), laparoscopy, or even open laparotomy [2, 3].

The negative impact of hydrosalpinx on pregnancy rates following IVF might be attributed either to reflux of the hydrosalpinx fluid causing mechanical washout of the transferred embryos or embryo-toxic effects [4]. In addition, endometrial receptivity may be markedly disturbed by hydrosalpinx. The best endometrial markers, integrins, decrease significantly in cases of hydrosalpinx [5].

In women with hydrosalpinx, the expression of peri-implantation endometrial Hoxa-10, a gene necessary for implantation success, increases after salpingectomy [6]. There is a significant improvement in IVF outcomes in patients with hydrosalpinx using laparoscopy either for tubal ligation or salpingectomy prior to IVF [7, 8]. However, laparoscopy represents an invasive procedure, with the possibility of visceral injury, especially if pelvic adhesions are encountered [9].

Hysteroscopy can also offer an effective and safe proximal tubal occlusion procedure in cases with hydrosalpinx. It has a lot of benefits, being a simple procedure with no need for general anesthesia, as well as being highly successful with rapid rehabilitation and less liability to injury [10].

In this study, we aimed to compare the success rate of hysteroscopic tubal occlusion using electro-coagulation versus laparoscopic tubal disconnection in cases of hydrosalpinx prior to IVF.

## Methods

A clinical trial was registered on ClinicalTrials.gov (NCT04037813) on 30/07/2019, and was conducted at Cairo University Hospital between September 2019 and January 2021 after approval of the Institutional Research Ethics Committee. All patients received counseling and gave their informed written consent before enrollment in the study.

The recruited patients in the study were aged 20 to 40 years. They were candidates for IVF procedure due to a history of primary or secondary infertility with the presence of communicating hydrosalpinx (unilateral or bilateral) diagnosed by HSG and transvaginal ultrasound showing distended tubes. Patients with any of the following were excluded: uterine anomalies, non-communicating hydrosalpinx, uncontrolled medical disorder interfering with pregnancy and difficulties with laparoscopy such as marked abdominal or pelvic adhesions due to different reasons (e.g., previous surgery, pelvic inflammatory disease, and pelvic endometriosis), uncontrolled cardiac or respiratory conditions, and morbid obesity.

## Study intervention

Patients included in this study were subjected to full medical, surgical, and gynecological history taking. Full physical and pelvic examinations were performed to examine the cervix and the vaginal walls, to detect pelvic organ abnormalities, and to evaluate the pelvic pain and vaginal discharge. Transvaginal ultrasound was done for all the recruited patients using an ultrasound machine (Voluson Pro-V and GE Voluson E10) to confirm hydrosalpinx. All patients had an HSG within the last 6 months showing unilateral or bilateral hydrosalpinx (the findings from pre-procedure HSG were used as a control).

Patients were equally randomized into two groups: group (A) with 54 patients who underwent hysteroscopic tubal occlusion of the hydrosalpinx and group (B) with 54 patients who underwent laparoscopic tubal disconnection. The randomization was done using 108 opaque sealed envelopes that were numbered serially from 1 to 108 and each envelope corresponding letter which denotes the allocated group was put according to computer-generated randomization table then all envelopes were closed and were put in one box, when the first patient arrived, after giving informed written consent, the first envelope was opened and the patient was allocated according to the letter inside.

For the hysteroscopy group, the procedure was performed under general anesthesia using standard, rigid 8-mm outer diameter with a 30° forward-oblique lens (Karl Storz, Germany) after cervical dilatation by Hegar dilators. A panoramic view of the uterine cavity was then obtained with visualization of both tubal ostia. The roller-ball (Ball Electrode, unipolar) was used to coagulate the interstitial part of the tube and cornual area using a 40- to 50-Watts current applied to each ostia for 3–5 s.

On the other hand, the laparoscopic management was done under general anesthesia, and closed umbilical entry technique with Veress needle was used.

The distended tube was identified and coagulated approximately 2.5–3 cm from the uterine cornu using bipolar coagulation and then cut by scissor, producing a proximal tubal cut.

The operative details in both groups were recorded, including actual operative time (calculated from the start of surgical intervention and not including the time of induction of anesthesia and sterilization), operative difficulty, and complications. All patients in both groups were followed up regarding the postoperative pain in the following 24 h (using VAS score assessment every 2 h) and the postoperative hospital stay. The success rate of tubal occlusion was assessed 1 month later using post-menstrual HSG (i.e., the presence of proximal tubal occlusion on post-procedure HSG).

### Study outcomes

The main study outcome was to compare the success rate of hysteroscopic tubal occlusion using electro-coagulation versus laparoscopic tubal disconnection. Secondary outcomes included comparing both groups regarding the operative time, complications as well as postoperative pain, and hospital stay.

### Statistical analysis

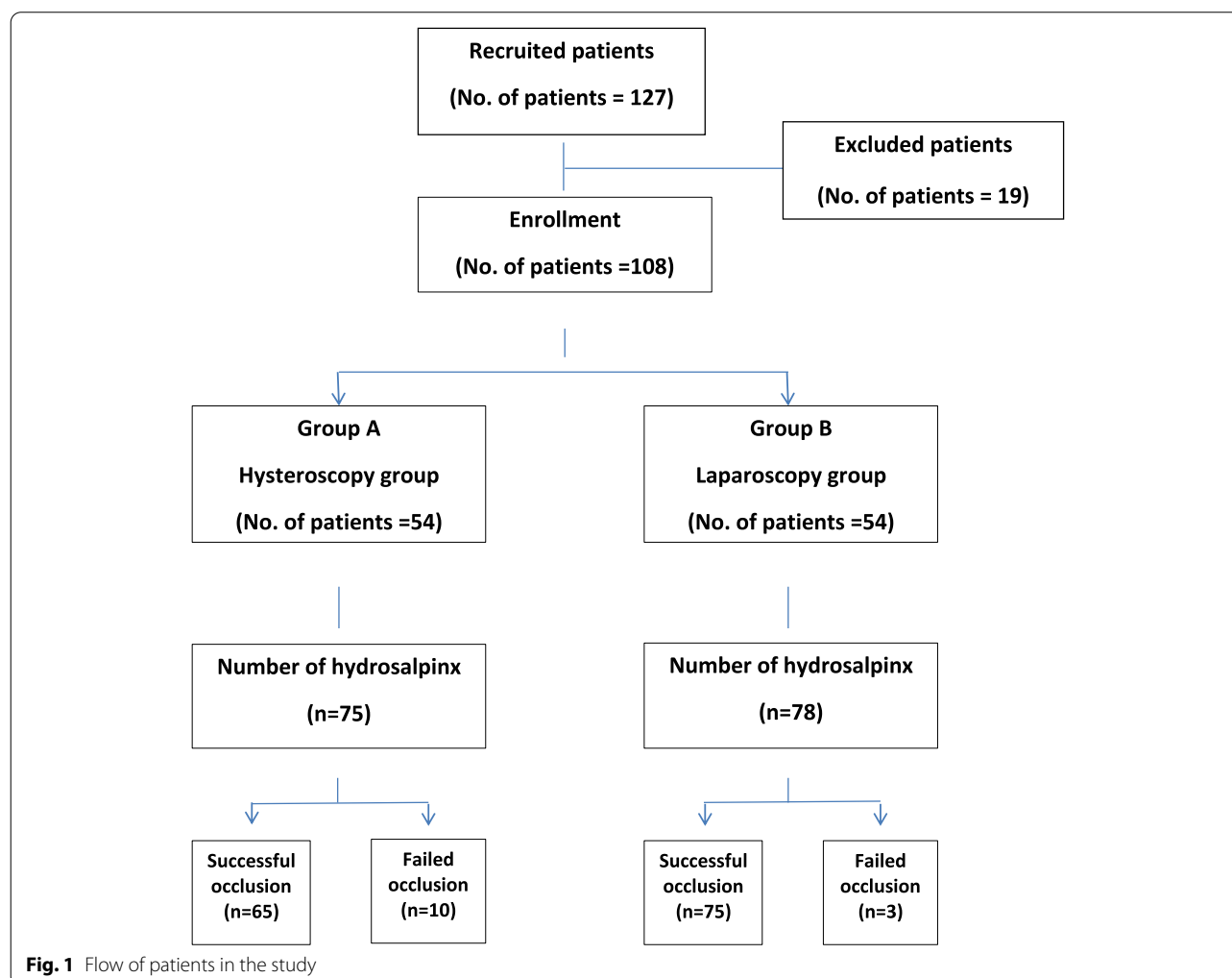
Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA). Data were summarized using mean, standard deviation, minimum and maximum for quantitative variables and frequencies (number of cases), and relative frequencies (percentages) for categorical variables. Comparisons between groups were done using the unpaired *t*-test [11]. For comparing categorical data, chi-square [2] test was performed. The exact test was used instead when the expected frequency was less than 5

[12]. *P*-values less than 0.05 were considered statistically significant.

### Results

Out of a total of 127 infertile patients with unilateral or bilateral hydrosalpinx presenting to the outpatient clinic at Cairo University hospitals and who were candidates for IVF were recruited, 19 patients were excluded as they did not meet the study criteria. The included 108 infertile women were then randomized into the two study groups. As regards the success rate in both groups, it was calculated from the total number of tubes occluded, not the total number of patients. The study followed CONSORT recommendations (Fig. 1).

The demographic data of the participants in both groups are presented in Table 1. There was no significant difference between both groups regarding age ( $P=0.754$ ); BMI ( $P=0.740$ ); parity ( $P=0.791$ ); the type of infertility, i.e., primary or secondary ( $P=0.7$ ); or the laterality



**Table 1** Demographic data in both groups

	Hysteroscopy group (n = 54)	Laparoscopy group (n = 54)	p value
<b>Age</b>	31.54 ± 4.62 (22–40)	31.26 ± 4.55 (21–40)	0.754
<b>BMI</b>	31.05 ± 5.03 (20.2–41.7)	30.73 ± 4.80 (20.6–41.3)	0.740
<b>Party</b>			
0	30 (55.6%)	28 (51.9%)	0.791
1	21 (38.9%)	24 (44.4%)	
2	3 (5.5%)	2 (3.7%)	
<b>Type of infertility</b>			
Primary	30 (55.6%)	28 (51.9%)	0.700
Secondary	24 (44.4%)	26 (48.1%)	
<b>Side</b>			
Unilateral	33 (61.1%)	30 (55.6%)	0.558
Bilateral	21 (38.9%)	24 (44.4%)	

**Table 2** The success rate of tubal occlusion in the studied groups<sup>a</sup>

	Hysteroscopy group (no. of hydrosalpinx = 75)	Laparoscopy group (no. of hydrosalpinx = 78)	p value
Succeeded	65 (86.67%)	75 (96.15%)	0.044
Failed	10 (13.33%)	3 (3.85%)	

<sup>a</sup> The success rate was calculated as the total number of tubes occluded not the total number of patients

of hydrosalpinx, i.e., unilateral or bilateral ( $P=0.558$ ) (Table 1).

As regards the success rate of tubal occlusion, 65 out of 75 tubes were successfully occluded (86.67%) using the hysteroscope, while in the laparoscopy group, 75 out of 78 tubes (96.15%) were successfully occluded, and accordingly, the laparoscopic disconnection was statistically more successful when compared to the hysteroscopic tubal occlusion ( $p=0.044$ ) (Table 2).

The hysteroscopic procedure for tubal occlusion was significantly shorter than the laparoscopic disconnection ( $3.65 \pm 1.03$  min vs.  $17.48 \pm 4.70$  min, respectively,  $P<0.001$ ). In addition, the hysteroscopic approach was significantly less painful than the laparoscopic one

(the mean postoperative VAS score was 1.81 vs. 4.06, respectively,  $P<0.001$ ). As for the postoperative hospital stay, it was almost the same in the hysteroscopy and laparoscopy groups ( $1.02 \pm 0.14$  vs.  $1.06 \pm 0.41$ , respectively,  $P=0.528$ ) (Table 3).

Both procedures were generally safe, and there was no statistically significant difference between both groups regarding the incidence of complications ( $P=1$ ). In the hysteroscopy group, only one patient was complicated by uterine perforation, while in the laparoscopy group, we had 2 patients with surgical complications (one patient had serosal bowel injury, and the other patient had port site infection) (Table 4).

**Table 4** The operative complications in the studied groups

	Hysteroscopy group (n = 54)	Laparoscopy group (n = 54)	p value
<b>Complications</b>			
Yes	1 (1.9%)	2 (3.7%)	1
No	53 (98.1%)	52 (96.3%)	

**Table 3** The operative time, postoperative VAS score (i.e., postoperative pain), and postoperative hospital stay (in days) in the studied groups

	Hysteroscopy group (n = 54)	Laparoscopy group (n = 54)	p value
Operative time	3.65 ± 1.03 (2–6)	17.48 ± 4.70 (11–40)	<0.001
VAS	1.81 ± 1.35 (0–4)	4.06 ± 1.65 (1–8)	<0.001
Postoperative hospital stay	1.02 ± 0.14 (1–2)	1.06 ± 0.41 (1–4)	0.528

## Discussion

### Practical implications of this work

The superiority of the laparoscopic approach over the hysteroscopic one for management of tubal hydrosalpinx prior to IVF cycles is well established in literature; however, our study compared a special method for hysteroscopic occlusion (*roller ball* electro-coagulation) to the standard laparoscopic approach. Similarly, our results proved the superiority of the laparoscopic approach but with an acceptable success rate for the hysteroscopic one using roller ball electro-coagulation, which could be a safe, simple, and cost-effective alternative to the standard laparoscopic approach. In terms of cost-effectiveness, this can be of special value in middle low-income countries like our country where the available resources are limited and the financial burden is a great concern.

### Interpretation of the results and comparison to available literature

There is enough data demonstrating that hydrosalpinx fluid dropped in the uterine cavity had a deleterious effects on female fertility, as well as the considerable improvement in fertility noticed following hydrosalpinx closure [13]. Although laparoscopic techniques (salpingectomy or disconnection) have been shown to be effective, the cumulative hazards for women undergoing IVF therapy remain a concern.

A pilot study by Aboulghar and his colleagues compared two hysteroscopic techniques for occluding a communicating hydrosalpinx among 10 patients planning for IVF: the roller-ball and the needle electrode coagulation of the cornual tubal end. They found that the success rate in the roller-ball group (6 tubes/4 patients) was less than that in the needle electrode group (10 tubes/6 patients) [14].

The current research studied the therapeutic effectiveness of two different strategies for managing hydrosalpinx before starting IVF cycles. We tried the hysteroscopic blockage of the cornual end of the diseased tube using roller-ball electro-coagulation and the laparoscopic disconnection of the hydrosalpinx. The ultimate goal of this trial was to evaluate both techniques regarding the success rate of tubal occlusion as confirmed by post-procedural HSG.

Our study is also among the few studies that evaluated the use of roller-ball electro-coagulation in hysteroscopic procedures. On the contrary, the previous studies used the Essure for hysteroscopic tubal occlusion and on which they based their results. So, our study suggested a safer and yet comparable alternative to the Essure devices.

Although we found the success rate for tubal occlusion was higher in the laparoscopy group (75 out of 78 hydrosalpinges, i.e., 96.15%) than in the hysteroscopy group (65 out of 75 hydrosalpinges, i.e., 86.67%), the significant difference between the two groups was just achieved ( $P=0.044$ ). This makes hysteroscopic management an acceptable alternative to the laparoscopic approach for patients in whom laparoscopy is technically difficult; the patient is unfit for surgery or refused the procedure. Furthermore, the mean operative time was 3.65 and 17.48 min, and the mean postoperative pain as measured by the VAS was 1.81 and 4.06 for the hysteroscopy and laparoscopy groups, respectively, with a highly statistically significant difference favoring the hysteroscopy group.

Similarly, El-Mazny and his colleagues compared the success rate of hysteroscopic tubal electro-coagulation for management of hydrosalpinx in infertile women undergoing IVF with laparoscopic management. They found the procedure was successful in 25 out of 27 hydrosalpinges (93%) in the hysteroscopic group and 78 out of 81 hydrosalpinges (96%) in the laparoscopic group. However, they found no significant difference between both groups [15].

Dreyer and his colleagues studied a total of 85 women who were divided into two groups: 42 women underwent hysteroscopic proximal occlusion by intra-tubal device placement (Essure), while the other 43 women underwent laparoscopic salpingectomy [16]. In agreement with our results, the median procedure time was significantly shorter in the group who underwent hysteroscopic proximal occlusion than the group who underwent laparoscopic salpingectomy (7 vs. 41 min respectively,  $P<0.001$ ). Furthermore, women who underwent hysteroscopic proximal occlusion via Essure were not hospitalized, while women who underwent laparoscopic salpingectomy had a median duration of hospitalization of 11 h ( $P<0.001$ ).

Although their results regarding the procedure time agreed with our results, the duration of postoperative hospital stay in our study was not statistically significant between the two study groups since all patients were routinely discharged on day one as per the hospital protocol for uncomplicated, minimally invasive surgical procedures.

Regarding the incidence of complications, we found no statistically significant difference between the two groups. This agreed with what Dreyer and his colleagues found in their study. There were three women in the group who underwent hysteroscopic proximal occlusion via Essure had a complication (two women failed, and one had PID). On the other hand, only one woman in the group of laparoscopic salpingectomy had a postoperative



infection at the site of umbilical entry and resolved without treatment [16].

In another trial, Wu and his colleagues explored other options for hysteroscopic tubal occlusion other than the Essure. They conducted a prospective study in which 56 women with either uni- or bilateral hydrosalpinx were included. The study evaluated the effectiveness of platinum fiber coil placement in 106 fallopian tubes of 55 patients scheduled for IVF. After 3 months, HSG examination revealed successful complete proximal occlusion in 52 patients. Out of them, 44 underwent IVF-ET with a clinical pregnancy rate of 60.5% (23/38) achieved and a live birth rate of 60.87% (14/23) reached. Based on such results, they concluded that using platinum fiber coil is a safe and valuable option for hysteroscopic proximal tubal occlusion in women with hydrosalpinx and scheduled for IVF [17].

Furthermore, a systematic review by Xu and colleagues which included more than 3000 patients showed that patients with hydrosalpinx and managed by hysteroscopic placement of Essure devices prior to IVF had lower clinical pregnancy and live birth rates than those managed by laparoscopic salpingectomy and laparoscopic proximal tubal occlusion [18]. Although our study did not compare both groups regarding pregnancy rates, our results agreed with the previously mentioned studies in proving the superiority of laparoscopic over hysteroscopic tubal occlusion of hydrosalpinx in patients preparing for IVF regarding the success of tubal occlusion.

Bao and his colleagues reviewed data from 10 women with hydrosalpinx who were unable to undergo laparotomy due to significant pelvic adhesions and were treated with surgical hysteroscopy prior to IVF and embryo transfer (IVF-ET). Interestingly, five out of them (50%) developed clinical pregnancy after their hysteroscopy procedure. They came to a conclusion that blocking the proximal part of the hydrosalpinx can successfully prevent hydros backflow into the endometrial cavity and help future implantation in assisted reproduction without causing substantial complications [19].

A French survey involving 45 hospital centers was done to assess the feasibility and results of Essure placement in patients with hydrosalpinx and scheduled for IVF when there are difficulties with laparoscopy. The study reported a retrospective analysis of 43 women who had 54 embryo transfers. The clinical pregnancy rate was 40.7%, implantation rate was 29.3%, and the live-birth rate was 25.9% [20].

### Strengths and limitations

The prospective nature of the study increased its significance among a pool of literature with a large number of retrospective analyses. Many of the available literature

restricted the pool of the patients who were candidates for hysteroscopic occlusion to those with a known contraindication to laparoscopic procedures. However, our study randomized patients with hydrosalpinx to either laparoscopic or hysteroscopic approaches, which added more strength to our work. Our study also was among the few studies that evaluated the use of roller-ball electro-coagulation in hysteroscopic procedures, which can provide a suitable alternative to the questionable Essure devices that were widely used previously for the same purpose. Our sample size was considered reliable to study the desired parameters with respect to the study population and when compared to previous studies.

Yet a possible limitation of the present study was that it lacked the evaluation of outcomes after IVF cycles such as fertilization rates, pregnancy rates, miscarriage rates, ectopic pregnancy rates, and live birth rates. Also, it did not study the possible long-term consequences that—though unlikely—may be related to the use of roller-ball electro-coagulation as we did not study the patients past the 1-month limit used for the postoperative HSG. Accordingly, future studies that assess pregnancy outcomes after IVF following tubal occlusion (hysteroscopic versus laparoscopic) together with studies that compare different methods of hysteroscopic tubal occlusion (e.g., roller-ball electro-coagulation, needle electro-coagulation, Essure and fibered platinum coil) are still warranted to achieve an evidence-based recommendation regarding the use of any of the previously mentioned methods over the other.

### Conclusion

Laparoscopic tubal disconnection remains the procedure of choice in patients with hydrosalpinx preparing for IVF. Although the success rates of the laparoscopic approach were significantly higher than in the hysteroscopy group yet, the hysteroscopic approach provides an acceptable and less painful alternative to the laparoscopic one, especially in cases where laparoscopy is technically difficult or refused by the patient.

### Acknowledgements

None.

### Clinical trial registration

It was first registered at ClinicalTrials.gov on 30/07/2019 with registration number NCT04037813.

### Authors' contributions

A.R., R.R., M.E., and Y.L. designed, conducted, and supervised the study. M.A. and M.A.A. conducted the study and analyzed the data. M.A.R. analyzed the data. All authors wrote and approved the manuscript.

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### Availability of data and materials

The datasets supporting the conclusions of this article are available in Kasr El-Ainy Hospital, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are, however, available from the authors upon reasonable request and with permission of Kasr El-Ainy Hospital.

### Declarations

#### Ethics approval and consent to participate

The study protocol was approved by Kasr El-Ainy Ethical Committee under registration number. All methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all participants.

All participants gave their consent after being informed of the study's objective and design, and they were given the option to leave the study at any time.

#### Consent for publication

Not applicable.

#### Competing interests

The authors declare no competing interests.

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