

Evaluating the Clinical Outcomes of Patent Ductus Arteriosus Surgical Closure in Yemeni Patients: A Retrospective Single-Center Study

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ABSTRACT

Background: Patent ductus arteriosus (PDA) surgical closure is a standard treatment approach for symptomatic neonates unresponsive to medical therapy. However, limited data on outcomes exist, particularly in resource-limited settings like Yemen. **Purpose:** This study aimed to evaluate isolated PDA surgical closure outcomes, including intensive care unit (ICU) stay, extubation, hospitalization, and postoperative complications. **Methods:** A retrospective study was conducted from May 2017 to May 2022 at Al-Thawra Modern General Hospital. Transthoracic echocardiography confirmed PDA diagnosis and assessed pulmonary hypertension severity. **Results:** A total of 290 patients underwent PDA closure, with the majority being female (65.5%, n=190) and infants (65.5%, n=190). The majority had moderate to severe pulmonary hypertension (61%, n=177). Primary intervention was PDA ligation with hemoclip application (82.1%, n=238). Most patients were extubated in the ICU (78.6%, n=228), discharged on the 5th day or earlier (90.3%, n=262), and 71% (n=206) required more than 12 hours in ICU. Complications occurred in 7.2% (n=21) of the cases, primarily residual duct issues and recurrent laryngeal nerve complications. Three cases (1.0%) resulted in non-surgery related deaths. Pulmonary hypertension significantly influenced hospital stay, extubation, and postoperative complications. **Conclusion:** Surgical PDA closure is safe and effective in Yemen. Pulmonary hypertension significantly influences outcomes, highlighting the importance of early detection and timely PDA management to prevent complications.

Keywords: Patent Ductus Arteriosus, Congenital Heart Defects, Infants, Yemeni Patient.

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INTRODUCTION

Patent ductus arteriosus (PDA) is a frequently encountered cardiovascular anomaly, and its presence is linked to unfavorable short-term and long-term consequences. These include the development of feeding difficulties, necrotizing enterocolitis, intracranial hemorrhage, reduced glomerular filtration rate, and bronchopulmonary dysplasia [1-4]. Preterm newborns have higher incidence of PDA since the normal physiological mechanisms that contribute to PDA closure, such as oxygen tension and decreased prostaglandins, are altered in premature infants [5]. Evidence revealed that the occurrence of PDA inversely linked to gestational age and weight [6].

Surgical PDA closure becomes necessary when symptomatic manifestations persist or medical treatment fails [7,8]. Even asymptomatic patients with considerable left-to-right shunting are recommended for closure to prevent future complications [9]. The outcomes of PDA closure have shown favorable results, particularly in cases with mildly elevated pulmonary vascular resistance and even some individuals with Eisenmenger's syndrome [10]. Closure reduces pulmonary blood flow and artery pressure, even in the presence of persistently high pulmonary vascular resistance [11]. However, the indications for closing small shunts, including those incidentally found ("silent"), particularly in older patients, remain less certain [12,13].

Given the advances in medical technology and surgical expertise, complications such as injury to the recurrent laryngeal nerve, chylothorax, residual duct, subcutaneous emphysema, and subcutaneous hematoma remain possible outcomes [14-16]. Moreover, transcatheter technique is expensive and requires a significant level of expertise [17].

This study focuses on the unique context of Yemen, a developing country in the middle east, where more than 80% of the population is estimated to live below the poverty line, and the ongoing conflict has further fractured the healthcare system [18-20]. Previous studies focused on the prevalence of congenital heart diseases [21-24]. However, a notable gap exists in understanding post-surgical outcomes of PDA closure. Therefore, the study aimed to evaluate the short-term surgical outcomes of PDA closure in Yemeni patients, focusing on postoperative complications, critical care duration, hospitalization length, and extubation location following various PDA ligation interventions.

MATERIALS AND METHODS

Study Design and setting

This retrospective single-center study was conducted at the Cardiac Center of Al-Thawra Modern General Hospital (TMGH) during the period from May 2017 to May 2022.

This hospital has 876 beds capacity and serves as the largest referral facility in Yemen's capital, Sana'a, acting as the primary destination for patients from all governorates.

Study Population

The medical records for all patients who were admitted to the cardiac center at TMGH for congenital cardiovascular anomalies within the study period were reviewed. Participants undergoing surgical intervention for isolated PDA were included. The study excluded individuals who had PDA accompanied by additional congenital cardiovascular anomalies. Preoperative confirmation of PDA diagnosis and assessment of pulmonary hypertension severity were performed using transthoracic echocardiography and clinical findings.

Sample Size and data collection method

The study included 290 patients admitted and underwent surgical intervention for isolated PDA at the TMGH cardiac center over a 5-year period. Data collection from patients' medical files included sociodemographic information, comorbidities, type of interventions, extubating location, ICU stay, hospitalization duration, and complications.

Surgical interventions

Patients were positioned in a right lateral decubitus position. A skin incision was made along the posterolateral area of the left chest, just below and running parallel to the inferior border of the scapula. The incision traverses through the latissimus dorsi and the posterior part of the serratus anterior muscle. The ribs were counted accurately and gained access to the fourth intercostal space. The left lung was gently retracted anteriorly to reveal the descending aorta. Subsequently, the mediastinal pleuron over the descending aorta was carefully opened, exposing the vagus nerve and the recurrent laryngeal nerve traversing over the ductus. Following thorough dissection, the ductus was then closed using one of the following methods:

Simple ligation: closing the duct by using silk suture Mersilk® (Ethicon, Johnson & Johnson) and polypropylene suture (PROLENETM 5-0 or 4-0, Ethicon Inc.). By using proline sutures, we made purse string at the end-sides of PDA; near to aortic and the pulmonary sides, and then we did simple ligation by using the silk suture in between previously purse string.

PDA ligation with hemoclip Application: closing the duct by using simple ligation as early described in addition to application of one or two medium-large titanium clips (Vitalitec International, Inc., France) in between the silk sutures.

PDA ligation with division: closing the duct by using simple ligation in addition to applying the cross-clamping at the end sides of PDA for bleeding control, followed by transection of the midpoint of PDA using proline 5-0 or 4-0.

The mediastinal pleura covering the descending aorta were precisely sealed. Subsequently, the lung was permitted to re-expand, and a small chest tube was inserted in all patients. The chest was closed using peri-costal absorbable sutures (VICRYLTM 1 or 2, polyglactin 910, Ethicon Inc.). The choice between sutures was based on the patients' requirements and the specific surgical case details. The muscle layers were carefully brought together using an absorbable suture technique, followed by the closure of the skin.

Data analysis

Data were imported into IBM SPSS Statistics version 27.0 for Windows® (IBM Corp., Armonk, NY, USA). Categorical variables, including age, gender, and PDA closure method were presented as frequencies and percentages. Outcome measures, such as ICU length of stay, overall hospital stay, extubation location, and postsurgical complications, were analyzed for associations with other independent variables (e.g., clinical and socio-demographic patient data) using chi-square and Fisher's exact tests where appropriate. A significance level of association was defined at a P-value of less than 0.05.

RESULTS

Table 1 shows the characteristics of the participants in

the study. Regarding the age distribution, the majority of participants were infants (65.5%, n=190), followed by children (17.6%, n=51), and neonates (16.9%, n=49). Gender distribution showed 65.5% females (n=190) and 34.5% males (n=100). The most common type of operation was PDA ligation with hemoclip application (82.1%, n=238), followed by simple ligation (16.2%, n=47).

Analysis of PDA diameter showed that 53.4% (n=155) had a moderate diameter, 29.7% (n=86) had a large diameter, and 16.9% (n=49) had a small diameter. Pulmonary hypertension was diagnosed in all patients, with 61.0% (n=177) experiencing moderate severity and 39.0% (n=113) having mild to moderate pulmonary hypertension. The majority were extubated in the ICU (78.6%, n=228), and 71.0% (n=206) stayed more than 12 hours in the ICU. A large proportion (90.3%, n=262) was discharged on the 5th day or earlier. Post-operative complications were observed in 7.2% of cases (n=21), with the most common issues being residual duct problems (28.6%, n=6), injury to the recurrent laryngeal nerve (19.0%, n=4), subcutaneous emphysema (19.0%, n=4), chylothorax (9.5%, n=2), and subcutaneous hematoma (9.5%, n=2). There were three deaths, constituting 1.0% of cases, all of which were unrelated to surgery.

Table 1. Participants' characteristics (n=290)

| | Variable | Count | (%) |
|---|--|-------|--------|
| Age (Years) | Neonate (≤ 4 weeks) | 49 | (16.9) |
| | Infant (5 weeks to 1 year) | 190 | (65.5) |
| | Child (1-12 years) | 51 | (17.6) |
| Gender | Male | 100 | (34.5) |
| | Female | 190 | (65.5) |
| Type of Intervention | PDA simple ligation | 47 | (16.2) |
| | PDA ligation with hemoclip application | 238 | (82.1) |
| | PDA ligation with division | 5 | (1.7) |
| Pulmonary hypertension | Mild | 113 | (39.0) |
| | Moderate to severe | 177 | (61.0) |
| Extubating location | In ICU | 228 | (78.6) |
| | In OT | 62 | (21.4) |
| Stay in ICU | less than 12 hours | 84 | (29.0) |
| | more than 12 hours | 206 | (71.0) |
| Discharge day | On the 5th day or earlier | 262 | (90.3) |
| | After the 5 th day | 28 | (9.7) |
| Post-operative complications | No | 269 | (92.8) |
| | Yes | 21 | (7.2) |
| Type of post-operative complications | Chylothorax | 2 | (9.5) |
| | Injury to recurrent laryngeal nerve | 4 | (19.0) |
| | Residual duct | 6 | (28.6) |
| | Subcutaneous emphysema | 4 | (19.0) |
| | Subcutaneous hematoma | 2 | (9.5) |
| Death prior to discharge | Death | 3 | (14.3) |
| | No | 287 | (99.0) |
| | Yes | 3 | (1.0) |

Abbreviation: OT: Operating Theater; ICU: Intensive Care Units; PDA: Patent Ductus Arteriosus.

The Association Between Participants' Characteristics and their Length of ICU Stay

Table 2 shows the association between patients' characteristics and their length of stay in the ICU, categorized as ≤ 12 hours and > 12 hours. Extubation location was significantly associated with the length of stay in the ICU ($\chi^2 = 159.860$, $p < 0.001$). Patients extubated in the operating

room experienced a shorter ICU duration compared to those extubated in the ICU. Additionally, post-operative complications were significantly associated with ICU stay duration ($\chi^2 = 9.232$, $p = 0.002$), indicating that patients with complications had a prolonged ICU stay. On the other hand, gender, age, type of PDA intervention, discharge day, and mortality before discharge did not exhibit a significant association with ICU stay duration ($p > 0.05$).

Table 2. Association between participant's characteristics and staying in the ICU

| | Variable | Stay in ICU | | | | Chi-square | P value |
|------------------------------|---|-----------------|--------|--------------|---------|------------|--------------------|
| | | ≤ 12 hours | | > 12 hours | | | |
| | | Count | (%) | Count | (%) | | |
| Age | Neonate | 12 | (24.5) | 37 | (75.5) | 2.744 | 0.254 |
| | Infant | 61 | (32.1) | 129 | (67.9) | | |
| | Child | 11 | (21.6) | 40 | (78.4) | | |
| Gender | Male | 28 | (28.0) | 72 | (72.0) | 0.069 | 0.793 |
| | Female | 56 | (29.5) | 134 | (70.5) | | |
| Type of Intervention | PDA simple ligation | 16 | (34.0) | 31 | (66.0) | 0.703 | 0.402 |
| | PDA ligation with hemoclip application/division | 68 | (28.0) | 175 | (72.0) | | |
| Pulmonary hypertension | Mild | 39 | (34.5) | 74 | (65.5) | 2.769 | 0.096 |
| | Moderate | 45 | (25.4) | 132 | (74.6) | | |
| Extubating location | In OT | 58 | (93.5) | 4 | (6.5) | 159.860 | <0.001* |
| | In ICU | 26 | (11.4) | 202 | (88.6) | | |
| Discharge day | On the 5th day or earlier | 80 | (30.5) | 182 | (69.5) | 3.246 | 0.072 |
| | After the 5 th days | 4 | (14.3) | 24 | (85.7) | | |
| Post-operative complications | No | 84 | (31.2) | 185 | (68.8) | 9.232 | 0.002* |
| | Yes | 0 | (0.0) | 21 | (100.0) | | |
| Death prior to discharge | No | 84 | (29.3) | 203 | (70.7) | 1.236 | 0.559 ^a |
| | Yes | 0 | (0.0) | 3 | (100.0) | | |

Notes: star sign (*) and bold color indicate significant association

Abbreviation: OT: Operating Theater; ICU: Intensive Care Units; PDA: Patent Ductus Arteriosus; a: Fisher's exact test was used.

Association Between Participants' Characteristics and Their length of Hospital stay

The relationship between participants' characteristics and the duration of hospitalization is shown in Table 3. Pulmonary hypertension showed a significant association with length of hospital stay ($\chi^2 = 5.806$, $P = 0.016$). Patients with moderate to severe pulmonary hypertension had a

greater likelihood of prolonged hospitalization. Additionally, post-operative complications were significantly associated with the length of hospital stay ($\chi^2 = 190.09$, $P < 0.001$). Patients who experienced post-operative complications were significantly more likely to require hospitalization for more than 5 days. Conversely, gender, age, extubating location, and type of surgical intervention did not exhibit a significant association with length of hospital stay ($P > 0.05$).

Table 3. Association between participant's characteristics and hospitalization stay

| | Variable | Discharge day | | | | Chi-square | P value |
|-------------------------------------|---|---------------------------------------|--------|-------------------------------|--------|------------|-------------------------------|
| | | On the 5 th day or earlier | | After the 5 th day | | | |
| | | Count | (%) | Count | (%) | | |
| Age | Neonate | 43 | (87.8) | 6 | (14.3) | 0.683 | 0.735 ^a |
| | Infant | 173 | (91.1) | 17 | (8.4) | | |
| | Child | 46 | (90.2) | 5 | (9.8) | | |
| Gender | Male | 92 | (92.0) | 8 | (8.0) | 0.479 | 0.489 |
| | Female | 170 | (89.5) | 20 | (10.5) | | |
| Type of Intervention | PDA simple ligation | 45 | (95.7) | 2 | (4.3) | 1.875 | 0.278 ^a |
| | PDA ligation with hemoclip application/division | 217 | (89.3) | 26 | (10.7) | | |
| Pulmonary hypertension | Mild | 108 | (95.6) | 5 | (4.4) | 5.806 | 0.016* |
| | Moderate to severe | 154 | (87.0) | 23 | (13.0) | | |
| Extubating location | In ICU | 202 | (88.6) | 26 | (11.4) | 3.737 | 0.053 |
| | In OT | 60 | (96.8) | 2 | (3.2) | | |
| Post-operative complications | No | 261 | (97.0) | 8 | (3.0) | 190.09 | <0.001*^a |
| | Yes | 1 | (4.8) | 20 | (95.2) | | |

Notes: star sign (*) and bold color indicate significant association

Abbreviation: OT: Operating Theater; ICU: Intensive Care Units; PDA: Patent Ductus Arteriosus; a: Fisher's exact test was used.

Associations between participants' characteristics and the extubation location

Table 4 reveals significant associations between participants' characteristics and the extubation location, either in the operating theater or ICU. Pulmonary hypertension severity exhibited a significant association with extubation location

($\chi^2 = 19.410$, $P < 0.001$). Patients with moderate to severe pulmonary hypertension were more likely to be extubated in the ICU, while those with mild pulmonary hypertension were more likely to be extubated in the operating theater. On the other hand, age, gender, type of intervention, and postoperative complications did not show significant associations with extubation location.

Table 4. Association between participant's characteristics and extubating location

| | Variable | Extubating location | | | | Chi-square | P value |
|-------------------------------------|---|---------------------|--------|--------|--------|------------|--------------------|
| | | In OT | | In ICU | | | |
| | | Count | (%) | Count | (%) | | |
| Age | Neonate | 9 | (18.4) | 40 | (81.6) | 1.848 | 0.397 |
| | Infant | 45 | (23.7) | 145 | (76.3) | | |
| | Child | 8 | (15.7) | 43 | (84.3) | | |
| Gender | Male | 16 | (16.0) | 84 | (84.0) | 2.628 | 0.105 |
| | Female | 46 | (24.2) | 144 | (75.8) | | |
| Type of Intervention | PDA simple ligation | 11 | (23.4) | 36 | (76.6) | 0.137 | 0.711 |
| | PDA ligation with hemoclip application/division | 51 | (21.0) | 192 | (79.0) | | |
| Pulmonary hypertension | Mild | 39 | (34.5) | 74 | (65.5) | 19.000 | <0.001* |
| | Moderate to severe | 23 | (13.0) | 154 | (87.0) | | |
| Post-operative complications | No | 60 | (22.3) | 209 | (77.7) | 1.893 | 0.169 ^a |
| | Yes | 2 | (9.5) | 19 | (90.5) | | |

Notes: star sign (*) and bold color indicate significant association

Abbreviation: OT: Operating Theater; ICU: Intensive Care Units; PDA: Patent Ductus Arteriosus; a: Fisher's exact test was used.

Association between participant characteristics and postoperative complications

Table 5 provides insights into the association between participant characteristics and the occurrence of postoperative complications. Pulmonary hypertension demonstrated a significant association with occurrence

of postoperative complications ($\chi^2 = 5.798$, $p = 0.016$). Patients with moderate to severe pulmonary hypertension were more likely to develop postoperative complications compared with mild pulmonary hypertension. On the other hand, age, gender, and type of intervention did not significantly impact postoperative complications.

Table 5. Association between participant's characteristics and post-operative complications

| | | Post-operative complications | | | | Chi-square | P value |
|------------------------|---|------------------------------|--------|-------|--------|------------|--------------------|
| | | No | | Yes | | | |
| | | Count | (%) | Count | (%) | | |
| Age | Neonate (≤ 4 weeks) | 46 | (93.9) | 3 | (6.1) | 0.755 | 0.752 ^a |
| | Infant (5 weeks to 1 year) | 177 | (93.2) | 13 | (6.8) | | |
| | Child (1-12 years) | 46 | (90.2) | 5 | (9.8) | | |
| Gender | Male | 95 | (95.0) | 5 | (5.0) | 1.142 | 0.285 |
| | Female | 174 | (91.6) | 16 | (8.4) | | |
| Type of Intervention | PDA simple ligation | 46 | (97.9) | 1 | (2.1) | 3.644 | 0.142 ^a |
| | PDA ligation with hemoclip application/division | 223 | (91.8) | 20 | (8.2) | | |
| Pulmonary hypertension | Mild | 110 | (97.3) | 3 | (2.7) | 5.798 | 0.016* |
| | Moderate to severe | 159 | (89.8) | 18 | (10.2) | | |

Notes: star sign (*) and bold color indicate significant association

Abbreviation: OT: Operating Theater; ICU: Intensive Care Units; PDA: Patent Ductus Arteriosus; b: Fisher's exact test was used.

DISCUSSION

This study conducted over the period from May 2017 to May 2022, revealed noteworthy findings regarding patients undergoing PDA closure in a cardiac center in Yemen. Although all patients attending to cardiac centers had pulmonary hypertension with a different severity level, those who have moderate to severe pulmonary hypertension experienced longer stays in both ICU and in the hospital. Additionally, they demonstrated postoperative complications and had a lower likelihood of being extubated in the operating room. Furthermore, patients with postoperative complications were more likely to stay in the ICU longer than those without complications.

In the current study, the majority of patients who underwent PDA closure were female. This observation aligns with recent research conducted in the United States, which found that PDA is twice as common among females compared with male [25]. Furthermore, a female predominance was noted in cases of PDA and coarctation of the aorta, reinforcing the observed demographic trend in our study [21,26].

This study showed that patients with mild pulmonary hypertension tend to spend a shorter duration in the ICU compared to those with moderate to severe pulmonary

hypertension. This might be interpreted as that the patients with mild pulmonary hypertension are clinically stable and less likely to develop pulmonary hypertension-related complications in this stage. Therefore, they are likely to stay shorter in the ICU compared to patients with moderate to severe pulmonary hypertension. Aligning with our findings, a study conducted in China among preterm infants, which emphasized the importance of pulmonary hypertension severity on patient outcomes [27].

A significant association between postoperative complications and the severity of pulmonary hypertension aligns with prior research by Lammers et al., highlighting increased symptom severity and mortality risks in patients with pulmonary hypertension [28].

The correlation between delayed presentation and complications has also been identified in studies in a developing country. This delay significantly complicates the management of congenital heart disease [29,30]. A previous study has shown that performing surgical ligation of the PDA in preterm infants three weeks earlier results in more favorable outcomes in nutrition and ventilation compared to delaying PDA closure by three weeks. This delay can lead to pulmonary overcirculation and alveolar edema,

compromising pulmonary function [31]. In Yemen, delayed presentation of PDA is likely to be attributed to patients-related socioeconomic factors and healthcare system-related factors. Primarily as a result of the ongoing war and political instability. The delay in seeking healthcare service in Yemen is not unique to PDA patients. A study has shown that 72% of patients with ST-elevation acute myocardial infarction in Yemen are admitted too late, impacting mortality rates compared to the Western hemisphere [32]. Therefore, addressing the causes of delayed presentation is crucial for improving outcomes associated with PDA closure.

This study also showed that patients with mild pulmonary hypertension were more likely to be extubated in the operating room compared to those with moderate to severe pulmonary hypertension. This interpretation hinges on the assumption that patients with mild pulmonary hypertension are less likely to have structural lung damage, unlike their counterparts with moderate to severe cases. Previous research has emphasized the role of chronic lung disease development in determining the timing of extubation after PDA closure [33].

The current study showed that patients who had shorter ICU stay were more likely to be extubated early in the operating room. This finding is consistent with the results of a recent Turkish study that investigated extubation strategies in patients with congenital heart disease. It demonstrated a significant correlation between reduced duration of ICU stay and the extubation strategy [34].

There are many different treatment approaches for PDA in premature neonates. While it is acceptable to simply ligate or hemoclip PDA in preterm infants, in older patients, a more comprehensive approach involving double or triple ligation, as well as division and oversewing, is recommended to reduce the risk of incomplete closure or recanalization [25]. In the current study, no significant association was observed between the method of PDA closure (simple ligation or PDA ligation with hemoclip application/division) with the measured outcomes, such as length of stay in the ICU and hospital, extubation and postoperative complications, emphasizing the safety of these techniques for PDA closure. The findings of this study are in agreement with recent studies endorsing surgical ligation and transcatheter occlusion as effective and comparable closure modalities, despite potential variations in hospital stays [35,36].

Complications were observed in 9.7% of patients, with residual duct, recurrent laryngeal nerve injury, and subcutaneous emphysema being the most common issues. Similar findings were observed from previous studies elsewhere [36-38]. Mortality in the current study aligns with that reported in the study by Zulqarnain and his colleagues

[37]. Another study in a developing country reported 4% as the 30-day post-operative mortality rate for congenital heart disease [29]. It's worth mentioning that the mortality assessed in our study is limited to in-hospital mortality and is not directly associated with the surgical procedure.

Study limitation

This retrospective study design introduces the potential for recall bias, given its reliance on past data and patient recollections. Additionally, this study focusses only on the short-term complication of the PDA closure without considering the longer-term surgical complications. Furthermore, the evaluation of pulmonary hypertension based on echocardiographic measurements presents limitations, including the risk of misinterpreting postcapillary pulmonary hypertension as pulmonary arterial hypertension. Nevertheless, previous research has indicated an acceptable level of accuracy for transthoracic echocardiography when compared to invasive assessments [39].

CONCLUSION

In patients with PDA, timely closure of PDA is pivotal in preventing pulmonary and cardiac complications. Although trans catheter closure has been associated with lower adverse outcomes, surgical closure continues to serve as the gold standard approach, particularly in resource-limited settings. Pulmonary hypertension has impact on the treatment outcomes, including length of hospital stay, extubation location, and the development of postoperative complications. Therefore, early detection and management of PDA is vital to prevent the development of complications. The establishments of a health network that facilitates smooth referrals from primary healthcare units to surgical centers can help achieve this goal. Further research is warranted to explore long-term outcomes and the suitability of specific techniques for different patient populations. Importantly, our study highlights those various surgical techniques yield favorable outcomes, with no significant differences observed in terms of ICU length of stay, overall hospital stays, extubation from ventilation, and postsurgical complications.

FUNDING

No funding was received for conducting this study.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ETHICAL CONSIDERATIONS

Scientific and administrative approvals were obtained from the Yemeni Council for Medical Specialization, Ministry

of Public Health and Population, and Al-Thawra Modern General Hospital prior to conducting the study. Patient names and personal information were kept confidential and solely used for research purposes.

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