

## REVIEW

# A systematic review and meta-analysis of short- and long-term complications of early versus delayed penile prosthesis implantation in patients with ischemic priapism

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**Summary** *Background: This study determined pooled estimates of short- and long-term complications of early versus delayed implantation of penile prosthesis in patients with ischemic priapism.*

*Methods: We searched Pubmed, ProQuest, Scopus, EBSCOHost, and other sources from January 1, 2013, to March 2023. All study designs were included except animal studies, review articles, and consensus documents. Of the 214 articles, four studies were included in the systematic review, and further meta-analysis included three studies (PROSPERO CRD42023411005).*

*Results: The short-term complication rate was lower with early implantation than with later implantation ( $\beta = -2.08$ ; 95% Confidence Interval [CI] = -3.54, -0.6;  $p < 0.05$ ). A similar value was also found in the pooled analysis for long-term outcomes, defined as overall satisfaction rate, which is better with early implantation than later ( $\beta = 2.18$ ; 95% CI = 1.35, 3.02;  $p < 0.05$ ).*

*Conclusions: The results of the pooled analysis confirmed that short-term complications were significantly lower with early implantation than with delayed implantation. Overall satisfaction rates were higher in early implantation than in delayed implantation of penile prostheses.*

**KEY WORDS:** Penile prosthesis; Early implantation; Delayed implantation; Ischemic priapism; Priapism.

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## BACKGROUND

"Priapism" describes a pathological condition characterized by a prolonged erection of more than four hours without sexual stimulation. This condition can be divided into subtypes of low, high, and intermittent flow (1). Ischemic priapism is the most common form of priapism and accounts for 90-95% of all cases. Although a common form, ischemic priapism is rare, with an overall incidence of 1.5 cases per 100.000 person-years (1, 2). Most cases of priapism have an idiopathic etiology; others may be related to hematologic abnormalities, intracavernosal injection of vasoactive drugs, illicit drug use, or malignancy (3, 4). Ischemic priapism is considered a form of compartment syndrome caused by hypoxia, hypercapnia, acidosis, and glucopenia in the erectile tissue. In the first 12 hours after

an episode of priapism, O<sub>2</sub> partial pressure decreases as the closed compartment prevents the supply of fresh, oxygenated blood, resulting in initial thickening and interstitial edema without smooth muscle necrosis (3, 5). Necrosis of the corpus cavernosum muscle was seen after 24 hours. After 24 hours, the risk of irreversible comprehensive smooth muscle changes leading to refractory erectile dysfunction is over 90%, and after 72 hours, there is no hope for recovery of erectile function (2, 3, 6). Failure to respond to aspiration and instillation of  $\alpha$ -agonists suggests that irreversible changes have occurred in the smooth muscle of the corpus cavernosum. At this stage, shunt surgery may successfully induce decongestion but will not reverse the ischemic damage, and refractory erectile dysfunction will persist in the long term (1, 4, 7). Refractory erectile dysfunction cannot be treated conservatively, and penile prosthesis implantation is the only way to achieve the stiffness required for penetrative intercourse. Penile prosthesis implantation at this stage can be very difficult due to diffuse corporal fibrosis, which complicates corporal dilation and is associated with an increased risk of distal/proximal cross-over complications and urethral perforation or injury (4, 8-10). In addition, the duration of the procedure significantly increases the risk of postoperative infection. In addition, fibrosis results in some shortening of the penis. After implantation, most patients still complain of penile shortening, which is one of the reasons for men's dissatisfaction with penile prostheses (11, 12).

Immediate implantation of a penile prosthesis is usually simple, reduces pain, and allows an earlier return to sexual activity. Despite the above advantages, immediate implantation of penile prostheses is associated with penile edema, increased risk of infection, and distal perforation, especially in patients with a history of shunt surgery (7, 13, 14). Delayed implantation of penile prostheses is now considered a surgical challenge with a high complication rate. Delayed implantation is also associated with suboptimal satisfaction. Several studies suggest that penile prostheses should be implanted in patients with refractory ischemic priapism at the acute stage when irreversible erectile smooth muscle damage has occurred (11, 15).

Currently, there is no general agreement on the timing of

penile prosthesis implantation in patients with ischemic priapism, as outcomes are variable. This review examines the current literature on priapism, with a focus on evaluating short-term and long-term outcomes in adult men undergoing direct implantation of a penile prosthesis for the treatment of acute ischemic priapism unresponsive to medical therapy or shunt surgery.

## METHODS

### Search strategy and selection criteria

Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for conducting meta-analyses (<http://www.prisma-statement.org/>), two independent reviewers performed data extraction (AJ, GW). Disagreements were resolved in a discussion among all investigators, and if necessary, they were analyzed and clarified by IW. For the literature search, we used the *PubMed*, *EbscoHost*, *Scopus*, and *ProQuest* databases from January 1, 2023, to March 2023. We also reviewed and manually searched the references and identified the possible dates from the conferences. The systematic search for terms and combinations used the following terms: "penile prosthesis"; "priapism"; "early"; "delayed"; "graft"; "satisfaction"; "complications".

Original research articles were included if they met the following criteria: (a) diagnosis of acute priapism, (b) comparison of penile prosthesis implantation: early vs. delayed, and (c) if the study provided information on clinical characteristics and outcomes of the two techniques. We excluded animal studies, review articles, and consensus documents. The exclusion criteria were as follows: (a) the study was a review article, letter to the editor, animal study, commentary, or consensus document; (b) the study did not focus on priapism patients or the diagnosis was unclear. If the patients were from the same hospital and the cases overlapped, we selected only the publication with the largest number of cases. The protocol was registered with the international prospective register of systematic reviews (PROSPERO), in accordance with PRISMA-P guidelines (PROSPERO CRD42023411005) (16). The protocol for this systematic review has been previously described (17). All identified studies are included in this review.

### Quality assessment and Risk of Bias

The five authors of the review classified each of the included studies as 'risk of bias'. Risk of bias in *Randomized Controlled Trial* (RCT) was assessed using the tools recommended in the Cochrane Handbook for Systematic Review of Interventions. Additional items were included to determine the risk that confounding factors may explain the results. ROBINS-1 quality ratings for non-randomized studies were used to assess the quality of observational studies. For each study, a pragmatic approach was used to assess the risk of confounding.

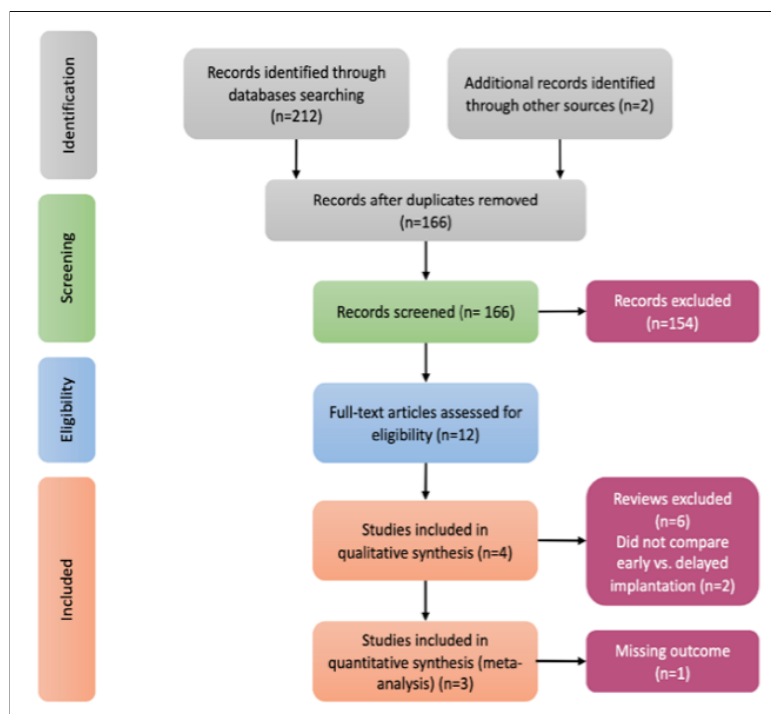
### Statistical analysis

The primary outcomes of interest in the study were short- and long-term complications of penile prostheses at early and late implantation. Short-term complications included pain, palpable nodules, residual curvature, infection, and erosion of the prosthesis, while long-term complications included quality of life, overall satisfaction, sexual satisfaction, penetration ability, erectile dysfunction, and increased curvature.

$I^2$  was used to assess heterogeneity between studies. A fixed-effects model was used when  $I^2$  was  $< 50\%$ , and when  $I^2$  was  $> 50\%$ , a random-effects model was chosen. In the fixed-effects model, population effect sizes were assumed to be the same for all studies. In contrast, the random-effects model attempted to generalize the results beyond the included studies by assuming that the selected studies were random samples from a larger population. If there was statistical heterogeneity in the results, a further sensitivity analysis was performed to determine the source of heterogeneity.

Sensitivity analyses were performed only for meta-analyses that evaluated primary/main outcomes (including outliers). Sensitivity analyses were performed in three different ways by excluding (1) each study individually, (2) studies identified as outliers, and (3) studies with a moderate and high risk of bias. After each analysis, the consistency and significance of the meta-analysis results are reassessed. A study is considered an outlier if the 95% *Confidence Interval* (CI) of the study is outside the 95% CI of the combined effect when the Forest Plot is viewed visually. The Forest plot shown refers only to the meta-analysis with outliers. After excluding significant clinical heterogeneity, the random-effects model with coefficient estimation ( $\beta$ ) was used as the effect size for the meta-

**Figure 1.**  
Flow diagram of study selection.



**Table 1.**  
Study characteristics.

Author, Year	Design	Patients	Duration of Priapism	Initial Treatment	Type of Implant	Short-term Complications	Long Term Complications
Zacharakis et al, 2014 (7)	Retrospective	68 (early), 27 (delayed)	7 days (early), 5 months (delayed)	Corporal aspiration and instillation of $\alpha$ -agonists and unsuccessful T-shunt surgery	Early: 64 malleable, 4 inflatable; Delayed: 12 malleable, 15 inflatable	Early: 6 infections Delayed: 80% patients required a second corporotomy and downsized cylinders due to dense fibrosis	Early: satisfaction rate in the ability of sexual intercourse 96% Delayed: 7 patients had erosion, mechanical failure. Satisfaction rate was 60%
Johnson et al, 2019 (25)	Retrospective	88 (early); 38 (delayed)	< 3 weeks (early); > 3weeks (delayed)	Not Available	Early: 83 malleable, 5 inflatable. Delayed: 19 malleable, 19 inflatable	Early: 8% required (n=7) required revision surgery due to infection (n=5), curvature (n=1) or erosion (n=1) Delayed: 23.7% (n=9) patients required revision surgery due to infection (n [ 6), erosion (n=2) or mechanical failure (n=1)	Early: Patient's satisfaction rate was 94.3% and the ability to have sexual intercourse was 93.2% Delayed: Overall 86.8% (n = 32) could have sexual intercourse and patient satisfaction rates were 60.5%
Elhawry & Fawzy, 2021 (26)	Retrospective	8 (early); 16 (Delayed)	31.7 $\pm$ 26.4 hours (early); > 6 months (delayed)	Aspiration, irrigation, open distal shunt, percutaneous distant shunt	Early: all malleable	There were no differences in the short-term complications of immediate versus delayed prosthesis placement except for difficulty with the insertion of the penile prosthesis in delayed procedures	There were no differences in the long-term complications of immediate versus delayed prosthesis placement except for difficulty with the insertion of the penile prosthesis in delayed procedures
Salman et al, 2022 (12)	Retrospective	23 (early); 19 (delayed)	5 $\pm$ 1.4 days (early); 177 $\pm$ 60 days (delayed)	Distal shunt	All malleable	Early: higher postoperative complications Delayed: higher intraoperative complications	Early: Patient satisfaction rate (92%); Delayed: 100%

analysis (ES). When  $p$  was  $< 0.05$ , the result was considered statistically significant (2-sided). All data were analysed using STATA ver. 15 software.

### Overview of the study selection

The PRISMA diagram for the entire study selection process is shown in Figure 1. An initial search of four databases yielded 212 studies, while additional records identified through references and conferences included two studies. Subsequently, 154 studies were excluded because they did not meet the requirements of the automation tool, and 48 duplicate studies were also excluded. Of the remaining 12 studies, a total of 6 studies were identified as reviews, and 2 studies did not compare early and delayed penile prostheses. Ultimately, four studies were selected and included in this systematic review and three studies were included in the meta-analysis.

### Studies characteristics

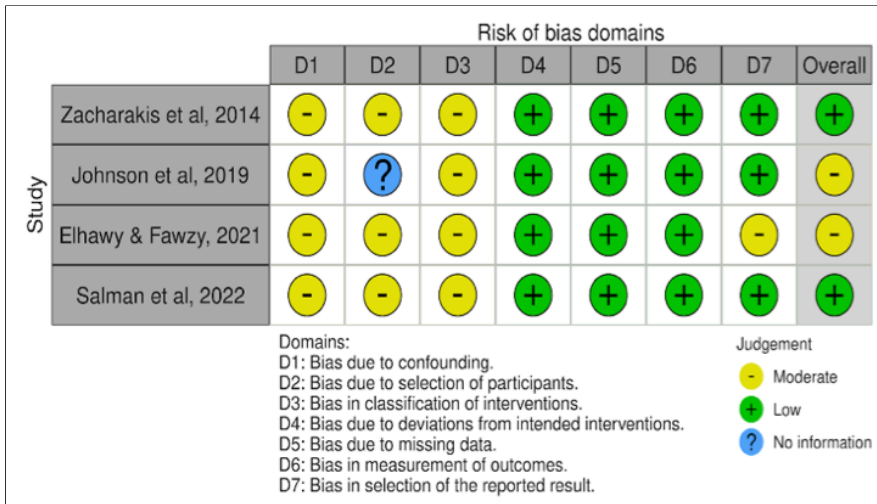
The characteristics of the included studies are summarized in Table 1. All included studies were retrospective studies using medical records. The total number of ischemic priapism patients from four studies was 287, with 187 patients undergoing early penile prosthesis implantation and 100 patients undergoing delayed penile prosthesis implantation. The operational definition for categorizing

patients as "early" or "delayed" was different in each study. The time from onset of priapism to implantation was 31 hours to less than three weeks in the early group. In the delayed group, it was 3 weeks to more than 6 months.

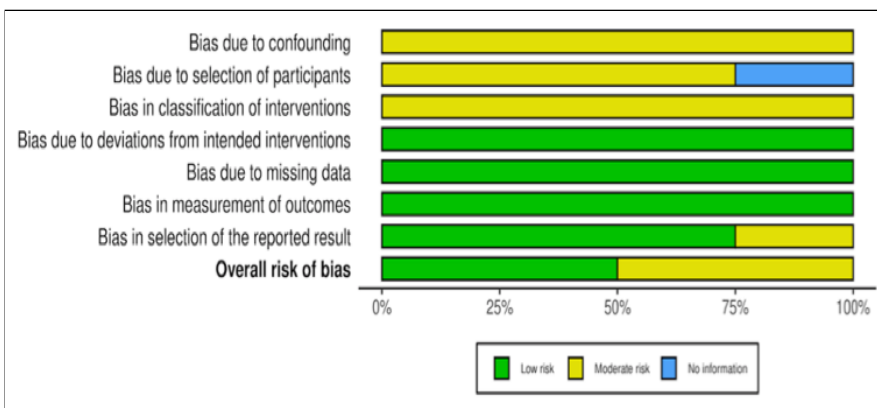
Three studies reported initial treatment before implantation in the form of physical aspiration, irrigation, instillation of  $\alpha$ -agonists, and T-shunt surgery (open distal and percutaneous). In patients with early implantation, 178 patients were treated with malleable implants and 9 others with inflatable implants. In patients with delayed implantation, 66 patients used malleable implants and 34 others used inflatable implants. Most studies stated that deformable implants were preferred because they are less expensive.

### Risk of Bias

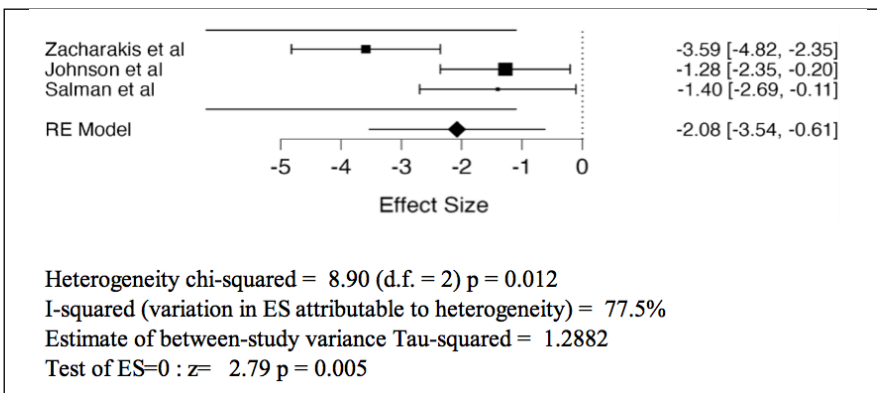
The risk of bias assessment is presented using two summary figures (Figures 2, 3) for each study according to all risk of bias domains. Two studies have a low risk of bias, and the other two studies have a potentially moderate risk of bias. When assessing the risk of confounding, all studies had a moderate risk of bias, mainly due to the type of penile prostheses that may have influenced study results. There is a moderate risk of bias in participant selection, with the exception of one study that did not include complete information on patient selection (published as a conference proceeding at a symposium). All studies have a moderate risk



**Figure 2.**  
 Risk of bias summary:  
 review authors' assessment  
 of each risk of bias  
 for each included study.



**Figure 3.**  
 Risk of bias chart:  
 review authors' assessment  
 of each risk of bias item,  
 presented as a percentage  
 of all included studies.



**Figure 4.**  
 Forest plot short-term  
 complications.

of bias in the classification of interventions, while the remaining domains have a low risk, except for one study that has a moderate risk of selection bias in outcome reporting. This study does not explain exactly how many patients in each group experienced complications but only reports the frequency of complications present, and more than one complication may occur in each patient.

**Short-term complications**

In the meta-analysis of short-term complications, all studies were included in the analysis. Nevertheless, the results of heterogeneity analysis using I<sup>2</sup> showed a high heterogeneity of 82.6%. Sensitivity analysis using Forest plots

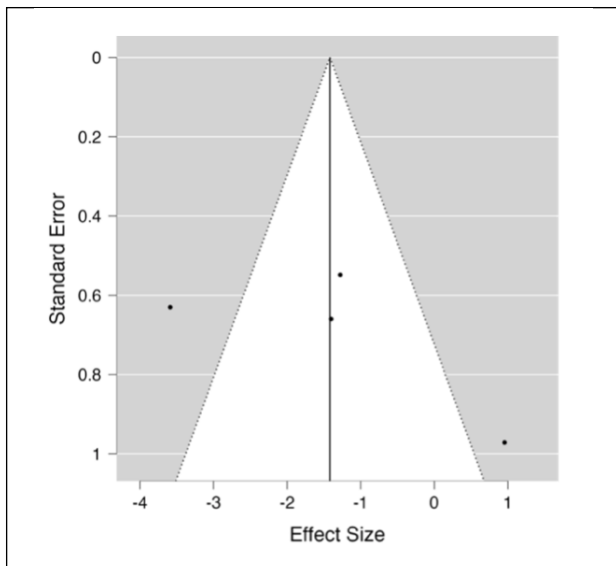
revealed that two studies were outliers. In the follow-up analysis, one outlier study was excluded due to the small sample size.

The results of a random-effects meta-analysis on short-term complications showed that complications were significantly lower with early implantation of penile prosthesis than with delayed implantation ( $\beta = -2.08 (-3.54, -0.61)$ ;  $p < 0.05$ ) (Figure 4). Funnel plot results are in Figure 5. shows asymmetric results, highlighting the potential for publication bias.

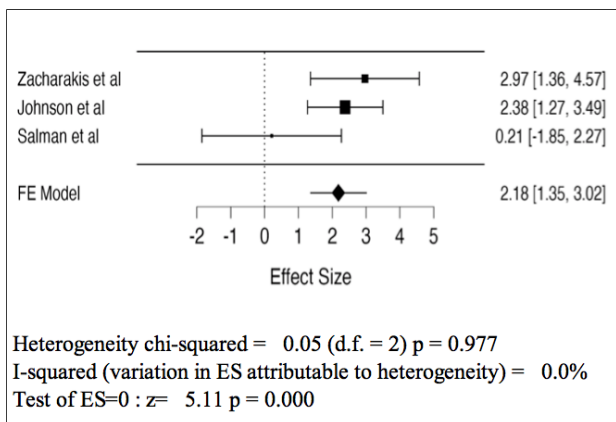
**Long-term complications**

The meta-analysis of long-term complications showed that

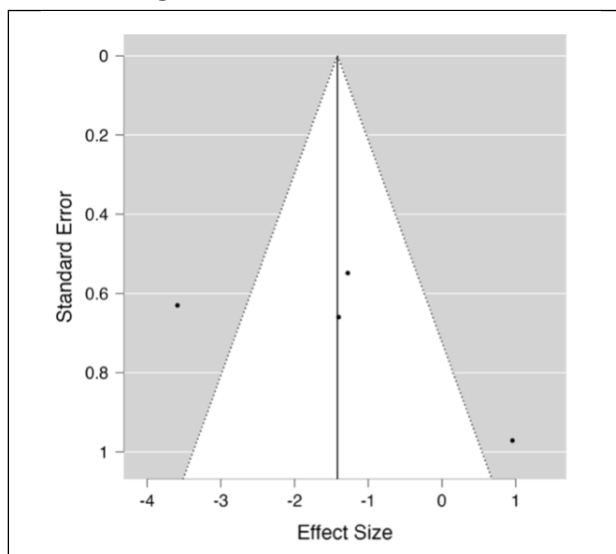
**Figure 5.**  
Funnel Plot short-term complications.



**Figure 6.**  
Forest Plot long-term complications.



**Figure 7.**  
Funnel Plot long-term complications.



patients were satisfied with the outcome of the prosthesis, including sexual intercourse and overall comfort. This analysis included three studies. In this case, there was no clear assessment of overall satisfaction in one study. The results of the meta-analysis on satisfaction rate showed that early implantation of the penile prosthesis had significantly better satisfaction than delayed implantation ( $\beta = 2.18$  (1.35, 3.02);  $p < 0.05$ ) (Figure 6). The results of the funnel plot show that there is no outliers (Figure 7).

**DISCUSSION**

The decision about penile prosthesis in an acute episode of ischemic priapism is still based on expert opinion that referred to small or retrospective studies, hence decision-making should be discussed between the patient and the urologist (11, 18). This study is the first systematic review and meta-analysis to exclusively include a comparative study of the short- and long-term complications of early and delayed penile prosthesis implantation.

According to a retrospective study conducted by *Palmisano et al.*, the immediate implantation of a soft penile prosthesis for patients with refractory ischemic priapism leads to instant pain alleviation, preservation of sexual function, and penile size, as well as higher surgical reproducibility in an emergency. Furthermore, ischemic priapism's financial and resource burden on the healthcare system may be decreased (19). The previous systematic review by *Capecce et al.* showed that all studies found superiority of early versus delayed penile prosthesis implantation in patients with ischemic priapism; however, this superiority was merely speculative because none of the studies were designed to compare the outcome of early versus delayed implantation (20). In this study, however, the pool effect size from a meta-analysis provided better certainty about the outcome of penile prosthesis implantation in the 287 patients with ischemic priapism. For both short-term and long-term complications, the pooled analysis showed significantly better outcomes for early implantation ( $p < 0.05$ ) than for delayed implantation.

Infection is the most common complication after early implantation of penile prostheses, especially in patients with postoperative aspiration, injection, or shunt (12, 21, 22). It can be caused by the penetration of bacteria through the skin into the sterile compartment and by cavernous edema, which prevents antibiotics from penetrating the cavernous tissue (1, 10, 21). Nevertheless, postoperative infections are generally treatable. The most challenging aspect of penile prosthesis implantation in delayed cases is existing corpus cavernosum fibrosis. Difficult physical dilatation with Hegars dilators can be replaced with cavernotomies to cover difficult dilatations, called corporal drilling (23, 24). This difficult situation can be complicated by urethral injuries, lateral or distal perforations, or cylindrical branches. Extensive corporal fibrosis and difficult dilation have resulted in the penile prosthesis being reduced in size to accommodate the corporal compartment (7, 20). This condition results in decreased penile length and is ultimately associated with lower overall patient satisfaction (7, 24). Indeed, in the study by *Salman et al.*, satisfaction after penile prostheses were found to reach 100% in patients with delayed



implantation, although this was also based on the baseline condition of the patient, who had a long history of penile fibrosis, shortening, and impotence (12).

To date, the exact timing of prosthesis insertion when fibrosis has occurred is not known with certainty. The timing of complete fibrosis after an acute attack of priapism is also unknown. *Sedigh et al.* described mild dilatation after one week of priapism (25), similar to the study performed by *Salman et al.* in which mild dilatation was performed within 5 days of establishing a diagnosis of priapism (12). Conflicting results were presented by *Hebert et al.*, who indicated a greater benefit in reducing the rate of severe complications when penile prosthesis implantation and reimplantation were performed within the first 4 months after the onset of corporal fibrosis (24). Although the benefits of early penile prosthesis surgery are well documented and continue to be studied, the psychological impact on patients with ischemic priapism who must make an urgent decision to undergo penile prosthesis surgery and then receive the results is an interesting topic. In the four studies included in this review, patients undergoing delayed penile prosthesis implantation were mostly unprepared for the surgery to be performed. From a psychological perspective, the impact of penile prosthesis implantation on patients' overall quality of life has not been studied. Currently, some reports recommend delaying the procedure for up to a week to give patients more time to understand their situation (11, 25). Although delayed treatment increases endogenous fibrosis, a delay may be justified if the psychological benefits of a longer duration outweigh the negative effects. Further studies on this topic should be initiated. This study has some limitations. Studies comparing early and delayed penile prosthesis implantation are very limited; moreover, all study designs performed are retrospective studies, which have their limitations in influencing confounding factors. The relatively large heterogeneity in short-term complications remains a limitation of the study. The differences may be due to patient demographic characteristics, surgeon experience, a technique used, type of implant, and timing of prosthesis insertion.

## CONCLUSIONS

This systematic review and meta-analysis is the first study to include a comparative examination of the short-term and long-term complications of early and delayed penile prosthesis implantation. The results of the pooled analysis confirmed that short-term and long-term complications were significantly lower with early implantation than with delayed implantation. Studies on the psychological impact of early penile prosthesis implantation are suggested for further investigation to optimize treatment outcomes for patients with ischemic priapism.

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**Conflict of interest:** The authors declare no potential conflict of interest.