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REVIEW

The process map of penile prosthesis implantation in outpatient surgery in Spain: a consensus document

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Abstract

Penile prosthesis (PP) implantation is feasible as an outpatient surgery. The present study describes the surgical process and establishes a consensus for improving the care circuit for outpatient PP implantation in Spain. A working group composed of a scientific committee with extensive experience in PP implantation and representatives of important scientific societies reached a consensus about the recommendations for outpatient PP implantation. The consensus was based on a structured methodology and evidence extracted from a systematic review, literature review and clinical experience. This study details the consensus reached regarding the profile of patients who are candidates for outpatient PP implantation; the care process in the presurgical, surgical and postsurgical phases; and the quality indicators for monitoring and evaluating the quality-of-care standards for outpatient PP implantation. Based on the insights of the working group, this study gives a description of the process map of outpatient PP implantation and promotes the map as a useful tool for urologist physicians and hospital managers.

Keywords

Consensus; Erectile dysfunction; Outpatient surgery; Penile prosthesis; Quality indicators

Mapa del proceso de implantación de prótesis de pene en cirugía mayor ambulatoria en España: documento de consenso

Resumen

La implantación de prótesis de pene (PP) es un procedimiento factible a realizar en el entorno de la cirugía mayor ambulatoria. El presente estudio describe el proceso quirúrgico y establece un consenso para mejorar el circuito asistencial de la implantación ambulatoria de PP en España. Un grupo de trabajo compuesto por un comité científico con amplia experiencia en la implantación de PP y representantes de importantes sociedades científicas consensuaron las recomendaciones para la implantación ambulatoria de PP. Se estableció un consenso basado en una metodología estructurada y en la evidencia extraída de una revisión sistemática, una revisión de la literatura y la experiencia clínica. Este estudio describe el consenso alcanzado en relación con el perfil de los pacientes candidatos a la implantación ambulatoria de PP; el proceso asistencial en las fases prequirúrgica, quirúrgica y posquirúrgica; así como los indicadores de calidad necesarios para el seguimiento y la evaluación de las normas de calidad asistencial para la implantación ambulatoria de PP. A partir de las reflexiones del grupo de trabajo, este estudio establece un mapa del proceso de implantación ambulatoria de PP y promueve el mapa como herramienta útil para los médicos urólogos y los gestores hospitalarios.

Palabras Clave

Consenso; Disfunción eréctil; Cirugía mayor ambulatoria, Prótesis de pene; Indicadores de calidad

1. Introduction

Penile prosthesis (PP) implantation is considered the gold standard for treating erectile dysfunction when pharmacological treatment fails and is contraindicated or poorly tolerated [1]. It is an effective option that allows patients to reproduce an erection and maintain sexual relationships, with high satisfaction rates in patients and their partners [2, 3].

Although patients initially undergoing PP implantation are required to remain in the hospital for monitoring and intravenous drug administration [4, 5], in recent years, this type of surgery has been promoted as an outpatient surgery, which has led to decreases in hospitalization costs and the length of stay [6].

Outpatient surgery, one of the current care modalities in the Spanish National Health System, accounts for close to half (47.6%) of all major surgeries performed in Spain [7]. Outpatient surgery is beneficial in that more patients can be treated, the waiting list for surgery is shorter, there are more conventional hospital beds available as well as resources for the most urgent and/or complex cases, scheduling is better and fewer surgeries are cancelled, leading to more efficient use of surgical equipment and facilities [6].

Generally, based on the type of care or postoperative surveillance, procedures classified as Davis level II and some type III can be performed as outpatient surgeries [8]. Although there is no specific Diagnosis-Related Group (DRG) (a case-mix complexity system implemented to categorize patients with similar clinical diagnoses) for PP implantation, according to the Davis classification, the procedure could be classified as type II, that is, as an intervention that can be performed under local, regional, general anesthesia or with sedation and that requires specific postoperative care, but not intensive or prolonged, with oral analgesia, if necessary [6].

Although there are few comparative studies of outpatient surgery and conventional inpatient surgery, evidence indicates that outpatient surgery is a safe modality of care when clinical protocols and organizational principles are followed [6]. Specifically, outpatient PP implantation would be similar in terms of safety and satisfaction with respect to its implementation in conventional hospitalization, according to the conclusions reached in a recently published systematic review [9]. Furthermore, an observational study conducted in Spain with the aim of assessing the feasibility, complications, and patient satisfaction with outpatient PP implantation showed adequate postoperative pain control and acceptable patient satisfaction rates [4].

Currently, there is a need to promote outpatient PP implantation to shorten waiting lists and allow patients to have faster access to a procedure that will significantly improve their quality of life. Since the standards and recommendations in the outpatient surgery units published to date are established in general terms, it would be advisable to describe the outpatient PP implantation process from its surgical indication to 24/72 hours after the intervention.

The objective of this study was to describe the surgical process and establish a consensus for improving the care circuit of outpatient PP implantation in Spain.

2. Materials and methods

2.1 Thematic framework

A recommendation is understood to be any statement in the medical or scientific field that responds to a known level of evidence or that is validated by experts in that field of knowledge based on their empirical experience [10]. The recommendations detailed in the present document were made based on the following questions: (1) What is the characteristics of patients who are candidates for outpatient PP implantation? (2) What is the care process in the presurgical, surgical, and postsurgical phases of outpatient PP implantation? (3) What are the quality indicators for outpatient PP implantation?

The care process of outpatient PP implantation should integrate the processes, subprocesses and activities, as well as each of the health care professionals involved in the care, from the moment surgical intervention is indicated until the patient is discharged from care 24/72 hours after surgery. The activities to be performed, the professionals involved, the criteria, and the location of each of these activities are described sequentially in a graphic map for each of the phases or subprocesses distinguished (presurgical, surgical and postsurgical phases).

2.2 Working group

The present recommendations for outpatient PP implantation were based on the consensus of two work teams: the scientific committee and the validation group. The scientific committee was composed of four experts in urology and andrology, and its main functions consisted of supervising the quality and suitability of the processes applied, as well as the validation of intermediate materials and final documents. The validation group was composed of representatives of four scientific societies: the Spanish Association of Major Ambulatory Surgery (ASECMA), the Spanish Society for Health Care Quality (SECA), the Spanish Association of Surgical Nursing (AEEQ) and the Spanish Society of Anesthesiology, Resuscitation and Therapeutics of Pain (SEDAR). Their functions focused on the review, discussion and validation of the recommendation proposed by the scientific committee following the different phases of the process, as well as the validation of the final document.

2.3 Consensus building

A previous systematic review was performed [9] to identify available scientific evidence regarding outpatient PP implantation. Given the practical orientation of the study and the scarcity of available bibliographic content on outpatient PP implantation, an additional review of the literature was performed with the aim of identifying clinical practice guidelines and consensus. After that, a formal agreement was reached through a participatory and structured methodology, which is detailed in Fig. 1.

The present document incorporates the contexts and evidence highlighted during the consensus process. All authors reviewed the complete material, and all pertinent modifications were made to achieve the maximum possible consensus.

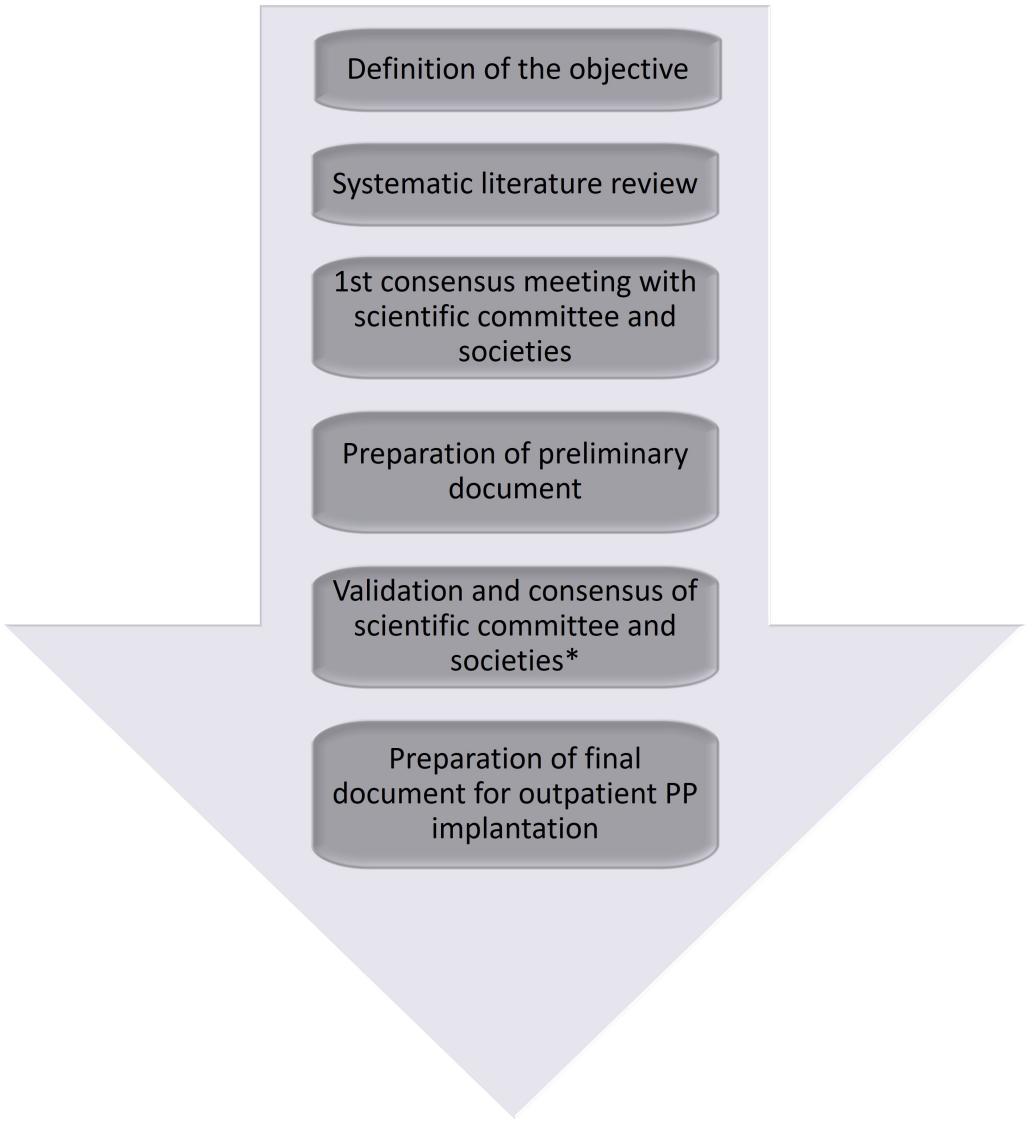

FIGURE 1. Consensus methodology. *The preliminary document was validated by a consensus meeting with the scientific committee and thereafter validated by scientific societies.

3. Recommendations

3.1 Recommendation 1: patient profile for outpatient PP implantation

Patients with a body mass index (BMI) >50, severe aortic stenosis, pulmonary hypertension, mitral regurgitation, acute myocardial infarction within the last 90 days, other cardiac and pulmonary comorbidities, or cerebrovascular accidents should be excluded [11]. Similarly, patients who received anticoagulants or antiplatelets should be excluded, except for those at low thromboembolic and thrombotic risk who stopped taking such drugs [12]. If necessary, prophylactic doses of low-molecular-weight heparin could be administered [12]. Patients with type III obesity and a BMI over 40 (morbid obesity) are not suitable for outpatient PP implantation; however, patients should be evaluated on an individual basis.

Only virgin cases and patients who underwent revision due to mechanical failure and who did not require other technically difficult adjuvant maneuvers should be selected.

Considering the anesthetic criteria and according to the American Society of Anesthesiologists classification, patients should be classified as grade I (healthy patients without any organic, biochemical or psychiatric alteration, different from the localized process that is a subsidiary of surgery) or II (patients with mild or moderate systemic alteration, which does not cause disability or functional limitation) [13]. Some of the patients classified as grade III (patients with severe alteration or disease of any cause that produces a defined functional limitation, to some degree) who are stable could be scheduled for outpatient surgery, individually assessing the benefits and risks of outpatient care.

The patient must accept and understand the outpatient surgery procedure and express his or her preferences. The sociofamilial support is important. Patients who lived more than 1 hour away from the hospital should be excluded from outpatient surgery, and in some cases, a restriction of a distance of less than half an hour may be needed. It is essential that the patient be accompanied. At the time of discharge from the outpatient surgery, there must be a responsible person who will remain with the patient for the first 48 postoperative

hours.

3.2 Recommendation 2: care process for outpatient PP implantation

3.2.1 Presurgical phase

This phase ranges from inclusion in the care process through patient evaluation and indication for outpatient surgery to the period of admission to outpatient surgery (Fig. 2). After the selection of patients by the urologist, an anesthesia consultation must be performed where the selection is confirmed or rejected. In those outpatient surgeries where this information is available, a specific nursing consultation will be performed. It is vital to provide exhaustive information to patients and family members, as well as informed consent [14].

3.2.2 Surgical phase

The surgical phase is divided into the PP implantation surgery itself and the recovery phase in the immediate postoperative period (Fig. 3). In this process, it is essential to identify the patient, check the items that make up the surgical checklist before moving the patient to the operating room area, verify the surgical site and the instruments to be used, and ensure the comfort of both the patient and his caregivers and the joint decision of the surgeon and the anesthesiologist to discharge the patient.

3.2.3 Postsurgical phase

The activities to be performed in this phase are centered on evaluating the correct evolution of the patient after the PPI surgical procedure, focusing on the active recovery of the patient, pain control and the detection of possible postoperative complications. Depending on the outpatient surgery and the organizational level of the hospital, the activities to be performed in the postoperative phase may vary slightly between centers. Both options, differentiated in Fig. 4, are focused on achieving the correct rehabilitation of the patient.

3.3 Recommendation 3: quality indicators for outpatient PP implantation

To guarantee patient safety, it is necessary to continuously monitor and evaluate quality-of-care standards in outpatient surgery, with the aim of detecting possible problems and applying the necessary improvements to avoid or solve them. Given their large number of quality indicators, the working group selected the most relevant and useful indicators for the PP implantation process, which are detailed in Table 1.

All quality indicators are relative to those of patients undergoing PP implantation surgery and may be used by a doctor or hospital center, which may use the quality standards of surgeries or procedures of similar complexity as a reference.

4. Discussion

PP implantation is an effective alternative for patients who have not previously responded to oral or injectable treatments [1].

Having recently completed 50 years of history since the first surgical procedure for the placement of a three-component hydraulic PP performed by Dr. Scott in 1973 [5, 15], PP implant surgery has incorporated numerous modifications, both in the surgical process of placement and in the development and efficacy of its mechanism. These improvements have managed to reduce to a minimum the complications derived from its placement and have made PP one of the treatments for erectile dysfunction with the highest rate of satisfaction for the patient and his partner [1, 16–18].

Among the historical milestones that mark the success and popularization of the PP we find the development of hydraulic systems for inflating and deflating the cylinders, which offer a more natural result to the state of erection and flaccidity of

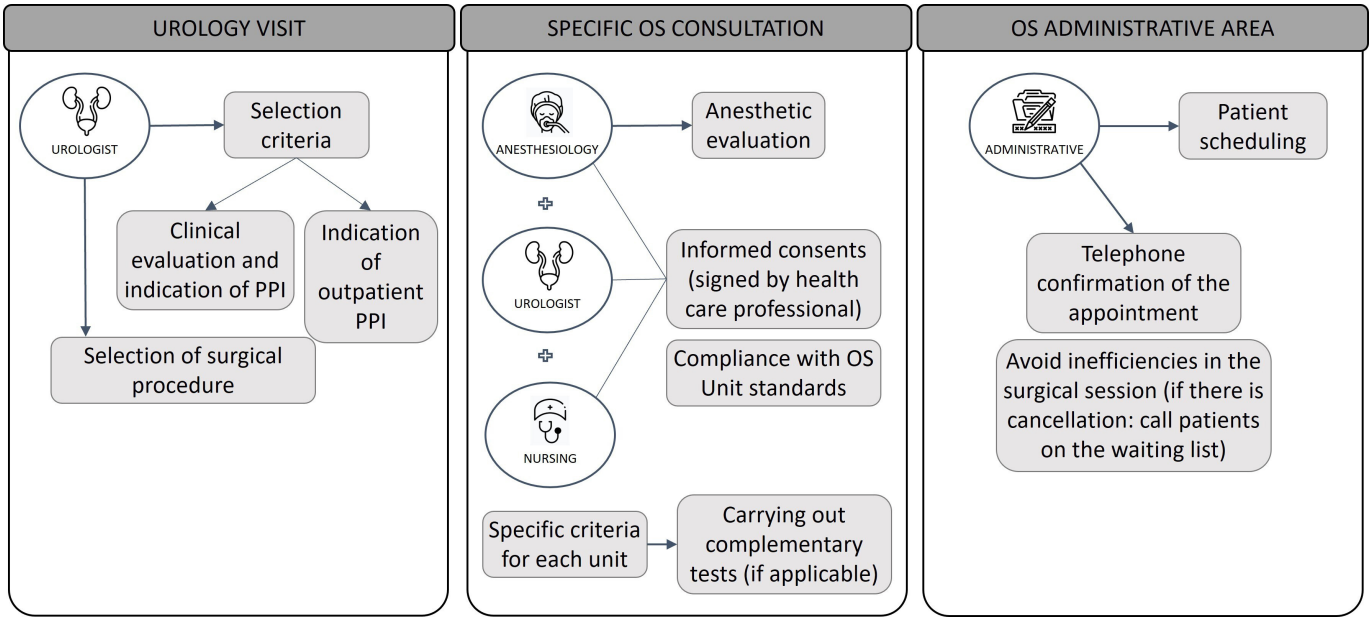

FIGURE 2. Process map of PP implantation in outpatient surgery in the presurgical phase. OS: outpatient surgery; PPI: penile prosthesis implantation.

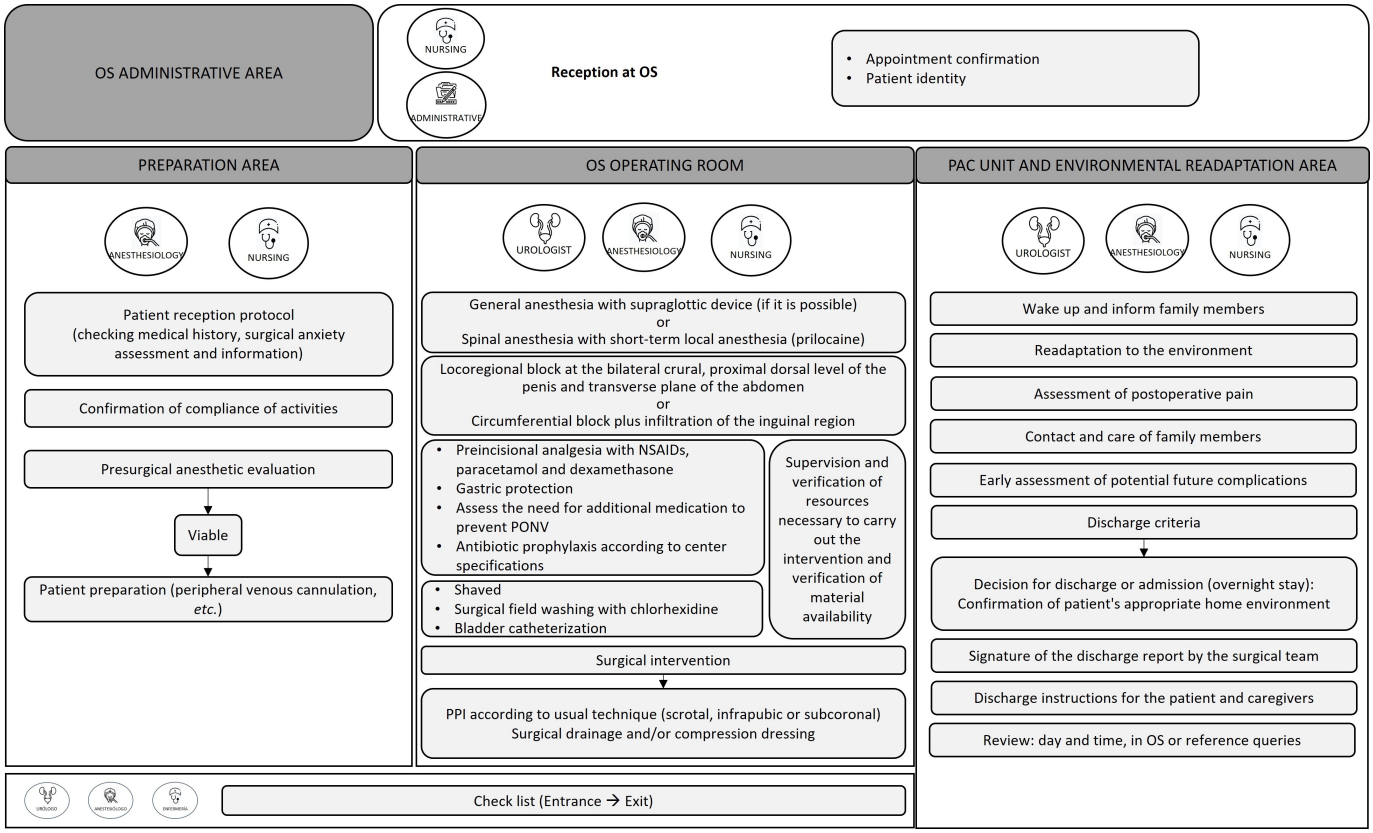

FIGURE 3. Process map of PP implantation in outpatient surgery in the surgical phase. NSAIDs: nonsteroidal anti-inflammatory drugs; OS: outpatient surgery; PAC: postanesthesia care; PPI: penile prosthesis implantation; PONV: postoperative nausea and vomiting.

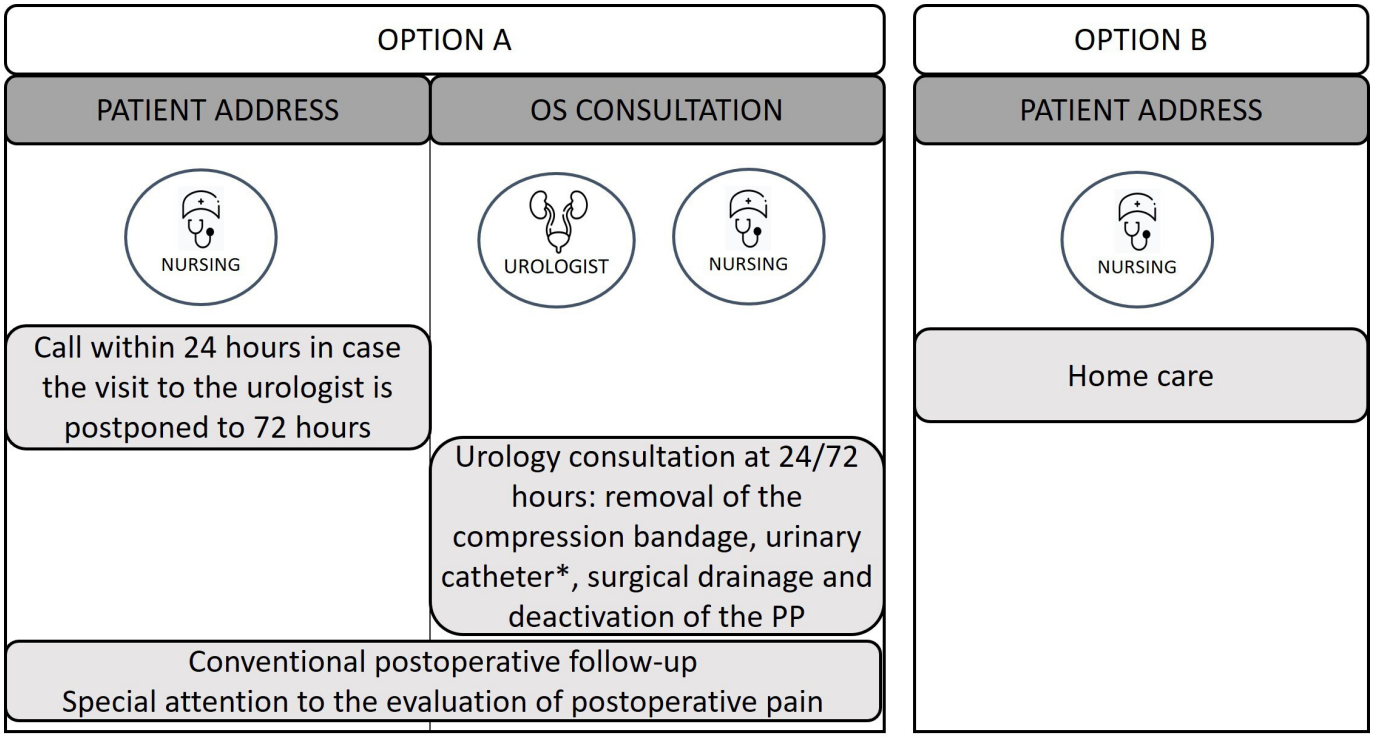

FIGURE 4. Process map of PP implantation in outpatient surgery in the postoperative phase. In both options it could be important to explicitly guarantee the telephone availability of a member of the surgical team in the 24–48 hours following discharge. *If the medical team decided to discharge the patient with the bladder catheter. OS: outpatient surgery; PP: penile prosthesis.

TABLE 1. Quality indicators for outpatient surgery.

Description	Formula	Data source	Periodicity
1. Evaluation of the efficiency and scientific-technical quality of the outpatient surgery			
Indicator: Cancellation of procedures			
Number of unscheduled interventions in surgical interventions already scheduled	Quotient between the number of surgical interventions that are suspended having been scheduled, and the total number of scheduled surgical interventions	Surgical Activity Record	Daily, monthly, quarterly, or annual measurement, as designated by the center
Indicator: Reinterventions			
Rate of reinterventions in the early postsurgical period (24/72 h)	Quotient between the number of patients with PPI reintervention in the outpatient surgery, and the total number of patients undergoing PPI surgery in the outpatient surgery	Balanced scorecards, information systems (EMR), MBDS, other sources (IAmetrics, SAP, OMI-AP, *etc.*)	Daily, monthly, quarterly or annual measurement, as designated by the center
Indicator: Unplanned overnight stay			
Rate of unplanned inpatient admissions following PPI surgery for surgical, anesthetic or sociofamilial reasons	Quotient between the number of patients undergoing PPI surgery under outpatient surgery admitted without being planned, and the total number of patients undergoing PPI surgery under outpatient surgery	Balanced scorecards, information systems (EMR), MBDS, other sources (IAmetrics, SAP, OMI-AP, *etc.*)	Monthly, quarterly, or annual measurement, as designated by the center
Indicator: Hospital readmission			
Rate of hospital readmissions in a period between 24 h and 28 days after having undergone PPI surgery in outpatient surgery	Quotient between the number of patients with hospital readmission after having undergone PPI in outpatient surgery, and the number of patients undergoing PPI in outpatient surgery	Balanced scorecards, information systems (EMR), MBDS, other sources (IAmetrics, SAP, OMI-AP, *etc.*)	Monthly, quarterly, or annual measurement, as designated by the center
Indicator: Risk-adjusted complication rate			
Risk-adjusted postsurgical complication rate	Quotient between the number of patients with grade $\geq$2 complications according to the Clavien-Dindo classification, and the expected number of patients with complications according to the complication risk of each individual patient	Balanced scorecards, information systems (EMR), MBDS, other sources (IAmetrics, SAP, OMI-AP, *etc.*)	Six-monthly or annual measurement
Indicator: Postoperative pain management			
Postoperative pain index, evaluated by means of the VAS, giving a score from 0 (no pain) to 10 (worst possible pain)	Quotient between the number of patients with postoperative pain VAS >5, and the total number of patients operated	Electronic medical and nursing record	Measurement at 72 h, one week and one month after the intervention
2. Evaluation of system efficiency			
Indicator: PP implantation replacement rate			
Replacement rate	Quotient between the number of PPI in outpatient surgery, and the total number of scheduled PPI surgical procedures (outpatient surgery + surgeries with admission)	Balanced scorecards, information systems (EMR), MBDS, other sources (IAmetrics, SAP, OMI-AP, *etc.*)	Six-monthly or annual measurement

TABLE 1. Continued.

Description	Formula	Data source	Periodicity
3. Evaluation of the quality perceived by the user			
Indicator: Satisfaction rate			
Degree of patient satisfaction evaluated using the NPS	Percentage of promoters (patients who rate 9 or 10) minus the percentage of detractors (patients who rate less than 7) with respect to the total number of surveys answered (hospitalization, consultations, emergencies, outpatient surgery and day hospital) and that the reasons are care-related	Satisfaction survey	Annual measurement

PPI: penile prosthesis implantation; EMR: electronic medical record; MBDS: minimum basic dataset; NPS: net promoter score; VAS: visual analog scale; SAP: systems, applications & products in data processing; OMI-AP: software for primary care health centers.

the penis compared with the semi-rigid PP, the incorporation of extenders to adjust the length of the PP more precisely once inflated, or the implementation of pumps and reservoirs with valve mechanisms that prevent accidental self-activation of the PP [19, 20]. All these advances have significantly improved the functional and aesthetic result of the implants.

However, it was the development of antibiotic-coated PPs (rifampicin and minocycline), together with the implementation of strict protocols for antibiotic prophylaxis and presurgical preparation (shaving and thorough washing of the surgical area), which changed the paradigm of this surgery and contributed to achieve the current low rates of postoperative infection and the consequent, in many cases, removal of the implant [21, 22]. On the other hand, the current development and application of selective anesthetic techniques, using locoregional blocks, have allowed a better control of postoperative pain, reduced hospital stay and even converted these interventions into outpatient procedures.

These advances achieved over the years have provided the PP implantation process with greater efficacy and safety, a reduction in the rate of complications, an improvement in the postoperative evolution of the patient, and a greater satisfaction with the results, all of which have led to better control of postoperative pain, reduced infections rate, shortened hospital stay, and enabled the establishment of effective and safe outpatient programs for PP implantation [5]. Outpatient surgery is based on the objective of carrying out a surgical procedure with the same safety and efficacy as if it were performed on an inpatient setting. This results in economic savings and the release of material and human resources, without causing a detriment to the quality of the health care provided.

Previous studies on the clinical outcomes and economic benefits associated with PP surgery have concluded that compared with surgery in an inpatient setting, implantation in an outpatient setting can achieve similar outcomes in terms of safety and satisfaction [9] and reduce costs by €962 per patient in the Spanish National Health System [23]. Therefore, in view of the available evidence, outpatient PP implantation is feasible and associated with lower costs and shorter procedure times, adequate pain control and acceptable satisfaction rates [11].

Although PP implantation has traditionally been performed as an inpatient procedure, in recent years, the proportion of surgeries performed as outpatient surgery has increased notably [4]. In the absence of clinical practice guidelines about this procedure, the present consensus was developed with the attempt to generate evidence for medical and health care professionals involved in PP implantation in the different phases of the surgical process, with the ultimate goal of shortening waiting lists for PP implantation, providing patients with a quick and satisfactory solution that improves their quality of life and that of their partners.

Recommendations for outpatient PP implantation were established by consensus, which was reached after a systematic literature review and a formal agreement that included a participatory and structured methodology of urology, anesthesia and surgery experts. Due to the nature of the study, a limitation inherent to the methodology should be considered. There is little evidence about outpatient PP implantation, and the present recommendations have been established based on expert opinion, which is associated with level 5 evidence and grade D recommendation [24]. The present document represents a guide, and health care professionals should cautiously interpret the guide.

Therefore, and recapitulating everything previously argued, the establishment of outpatient PP implantation is a safe procedure, with success and complication rates similar to those of the inpatient setting.

Despite this limitation, the recommendations collected in the present document, which are based on an expert review of the literature and the clinical experience of specialists, marking a significant initial step toward defining the process for outpatient PP implantation.

5. Conclusions

Based on the insights of the working group, this study establishes a process map of outpatient PP implantation and promotes the map as a useful tool for urologist physicians and

hospital managers.

AVAILABILITY OF DATA AND MATERIALS

The data are contained within this article.

AUTHOR CONTRIBUTIONS

ÓG, MP, ET, MAC and JT—designed and conceptualized the research study. MP—wrote the draft of manuscript. ÓG, MZ, LAH, JML, JIMS, RM, IM and JT—contributed to acquisition, analysis and interpretation of data. All authors performed a critical revision of the manuscript and contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

ACKNOWLEDGMENT

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CONFLICT OF INTEREST

ÓG, MZ, LAH, JML, RM and IM declare no conflicts of interest. MP is employee of Pharmacoeconomics & Outcomes Research Iberia (PORIB), a consultancy firm specializing in health technology assessment, which has received unconditional funding from Boston Scientific Iberia & Italia. JIMS is serving as one of the Editorial Board members/Guest editors of this journal. We declare that JIMS had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to EFP. ET is employee of Boston Scientific Iberia & Italia. MAC is director of Pharmacoeconomics & Outcomes Research Iberia (PORIB), a consultancy firm specializing in health technology assessment, which has received unconditional funding from Boston Scientific Iberia & Italia. JT has received honorary/consulting fees from Boston Scientific.

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