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Full length article

Prospective feasability study of ambulatory surgery for pelvic organ prolapse

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ABSTRACT

Study objective: The aim of this study was the evaluation of ambulatory surgery (AS) rate for pelvic organ prolapse (POP).
Design: It was a prospective observational study.
Design classification: Level II-2.
Setting: Patients were divided in two groups: Group EAS: patients eligible to ambulatory surgery and Group NEAS: patients not eligible to AS.
Patients: all patients from August 2015 to November 2016 undergoing surgery for POP in our institution.
Measurements: The main outcome was overall AS rate in the population. Secondary outcomes were in NEAS group: reasons for ineligibility; in EAS group: AS success rate, reasons of failure and patient satisfaction related to AS; in each group: post operative re-admission or consultation, morbidity and global satisfaction.
Main results: There was 157patients included in the study. Eligibility criteria for AS was met for 111/157 (707%). Overall AS rate was 58% and success rate of AS was 82%. Reasons for ineligibility to AS were lack of home support (50%), home >1 h from hospital (109%), poor home conditions (2,2%), associated comorbidity (21.7%), associated procedure (4,3%) and refusal for AS (109%). Reasons for failure (20/111, 18%) of AS were unsuccessful trial of void (TOV) (65%), post operative nausea-vomiting (PONV) (15%), subcutaneous emphysema (5%), post-operative bleeding (5%) and faulty organization (10%).
There was no unscheduled re-admission the night after surgery in EAS group. 7,2% in EAS group and 13% in the NEAS group had an unscheduled consultation. There were 4 re-admissions (3,6%) in the EAS group and 1 (2,2%) in the NEAS group during follow-up.
Patient satisfaction to AS was 100% on next-day call and 923% at 6 weeks.
Conclusion: Ambulatory surgery rate was 58% in this population of surgically managed prolapses; AS success rate was 82%. There was no adverse events related to AS and patient satisfaction to AS at 6 weeks is high.

Introduction

Population-based epidemiologic studies report that almost 126% of women will undergo POP surgery by the age of 80 years and that the number of surgical procedures for POP will increase dramatically considering the aging of population [1,2]. This will lead to a significant increase of financial burden related to POP in health care cost [1].

POP AS rate vary widely among countries. Some are very advanced [3,8] but others show lower rates. In the US, POP AS rate was 156% in 2008 and is estimated 283% in 2010 [1]. In Europe AS rate is high in some countries (Denmark, Sweden), but low in others (Germany, Scotland), mainly due to economic features [4]. In France, POP AS rate is low (6,1% in 2015, 7,6% in 2016) [5].

The explanation can be cultural but is usually related to poor economic valuation of AS. Nevertheless, in most countries health authorities have decided to promote AS, in order to reduce health care costs. It has been shown that AS significantly reduces costs of several surgical procedures such as hernia surgery, cholecystectomy, laparoscopic tubal ligation or paediatric surgery [6]. Economic

Abbreviations: POP, pelvic organ prolapse; AS, ambulatory surgery; EAS, eligible to ambulatory surgery; Neas, not eligible to ambulatory surgery; PONV, post operative nausea/vomiting; SUI, stress urinary incontinence; VAS, visual analogic score; MUS, mid urethral sling; TOV, trial of void; GP, general practitioner.

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data's related to POP surgery are scarce [7]. Beside economics, AS is also associated with benefits for the patient: decrease in thombo-embolic and infectious complications [8,9] and higher patient satisfaction (10)

We report in this study the feasability of AS in a global population of surgically managed POP.

Materials and methods

Study design and setting

This was a prospective, single-center cohort study including all patients from August 2015 to November 2016 undergoing POP surgery in our unit.

All patients operated for POP were asked to participate.

Criteria for eligibility for the study were patient >18years, eligible to vaginal or laparoscopic prolapse surgery, who signed an informed consent form and understanding French.

Patients were divided in two groups: Eligible to AS (EAS) and Not Eligible to AS (NEAS). Criteria for eligibility to AS [11] were: social criteria (Home <100 km or 1 h, suitable home conditions, available home support), medical criteria (no pathology contra indicating AS, duration of surgery or associated surgery consistent with AS), and acceptance of AS by the patient.

Preoperative evaluation

Pre-operative evaluation recorded patients' characteristics, prior surgical history and clinical examination using the POP-Q system. If necessary, patients were subjected to multichannel urodynamics, urinalyses, pelvic sonography and cervical smear before surgery.

Surgical Procedures

Surgical approach (laparoscopic vs vaginal) concomitant hysterectomy or mid urethral sling (MUS) were not taken in account for eligibility to AS.

Surgical procedures have been classified as single (one procedure) or multiple (association of 2 or more separate procedures).

Concomitant sling placement was performed only in case of overt SUI without voiding dysfunction on urodynamics. In other cases, patients were informed that MUS could be placed if needed in a second step.

Peri-operative care

A standardized Anesthesia/ Analgesia/PONV protocol was used for the study in the EAS group.

General anesthesia using Aivoc Propofol and low dose of Sufentanyl and Ketamine was preferred; Midazolam was optional.

Multi-modal analgesia was used combining Naropein infiltration (pudendal or abdominal wall) and drugs (paracetamol, ketoprofen if possible, tramadol or nefopam in second line). Self administered morphine was indicated in case of VAS score > 3 in recovery room. ethasone + Droperidol were used as prevention of PONV.

Local anesthesia + sedation was possible in case of colpocleisis.

Regional anesthesia was possible at the patient request.

A Foley catheter was inserted for all patients; it was removed 2 h after the end of surgery in EAS patients and 24 h after surgery in NEAS patients.

A vaginal packing was used in case of vaginal surgery (except for colpocleisis); It was removed 2 h after the end of surgery in EAS patients and 24 h after surgery in NEAS patients.

Discharge

Patients in the EAS group were discharged on the same day if the Chung score [12] was ≥9 and after one successful TOV. In case of voiding dysfunction, patients were transferred to the inpatient unit and self catheterisation was considered.

Postoperative evaluation

Patient in EAS group were divided in two groups: EAS success (patient discharged on the same day) and EAS failure (patients with overnight admission)

Post-operative follow-up was scheduled at day 1 and 6 weeks.

Day 1 visit was made by phone by the AS unit nurse using a standardized questionnaire for EAS Success patients and in the hospital for others.

During 6 weeks visits, the surgeon who performed the procedure recorded post-operative events (re admission, complications, unscheduled visits, phone calls) and assessed POP-Q staging and mesh complications by vaginal examination. All patients were asked to complete PGI-I score [13] and EAS Success patients completed a specific questionnaire related to satisfaction to AS.

Reported Measures

The main measure was the overall AS rate in the population (Number of patient in AS / Number of patient included).

Secondary measures were

In NEAS group: reasons for non eligibility,

In EAS group: AS success rate (Number of patients in EAS success group/ number of patients EAS group), reasons for failure and predictive factors of failure, patient satisfaction at day 1 and 6 weeks.

Data of all EAS failures have been reviewed and classified as preventable (probably related to a defective care) or unpreventable (related to patient or procedure).

In all groups: peri-operative and post-operative complications, Health Care System use (consultation, re-admission, re-operation) from discharge to 6 week visit.

Ethics and statistical methods

Ethical approval was obtained from the CPP SUD MEDITERRANEE (N° 2014-A01939-38) and recorded in Clinical Trials.gov as N° NCT02926287. Signed informed consent form has been obtained from all patients.

The number of subjects required is based on an estimated AS success rate of 80% with an error of 8% and a standard risk of 5%.

A descriptive analysis of the population has been done. Qualitative variables are expressed as counts and percentages, as quantitative variables are expressed as means and standard deviations (SD), or range when mentioned. Variables are compared between EAS and NEAS groups or between EAS Success and EAS Failure groups using Anova or Kruskall-Wallis tests for quantitative variables and Fisher or Chi 2 tests for qualitative variables.

To explain the failure of the ambulatory surgery we carried out a logistic regression including all variables with $p < 0.2$ in univariate analysis. Statistical package SAS v.9 and chisquare tests were used for the univariate and multivariate analysis by statistical team of our institution.

Results

From August 2015 to November 2016 159 patients were eligible for prolapse surgery. Two were not included (1 refused

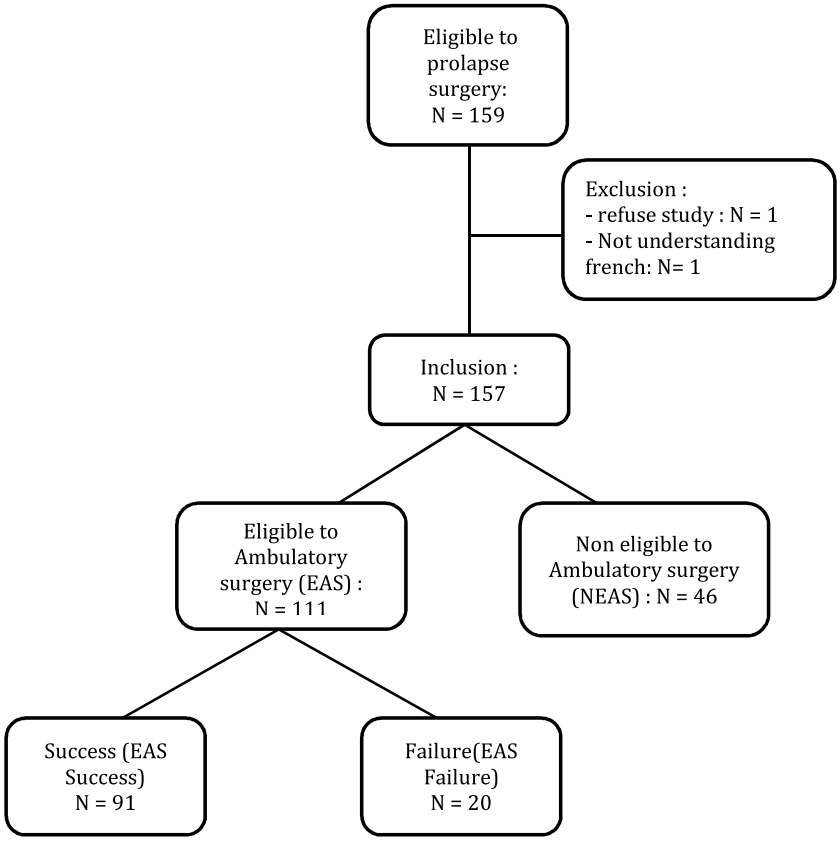

Fig. 1. Flow chart of the study.

participation, 1 not understanding French); 157 were included in the study. Flow chart of the study is reported in Fig. 1.

Baseline characteristics and procedures are reported on Table 1.

Eligibility to AS was met by111/157 (707%) patients and 46/157 (293%) had at least one criteria for non eligibility; they are reported in Table 2.

Only 5 patients without medical or social criteria of non eligibility refused ambulatory surgery.

AS surgery rate in overall population and in EAS group are reported in Table 3.

Over night stay was necessary for 20/111 (18%) patients in EAS group; the reasons for failure of AS are reported in Table 4. Among those patients 15/20 (75%) were discharged at day1. Unsuccessful trial of void (TOV) is the main reason for failure (13/20); 5/13 of those patients had a concomitant sling placement.

In univariate analysis predictive factors of failure were end of surgery after 12 AM, Anesthesia/analgesia/PONV protocol deviation

Table 1
Baseline characteristics and procedures.

Variable (mean ± SD or %, nb)		Overall Population n = 157	EAS group n = 111	NEAS group n = 46	p
Age (years)		672 ± 8,5	66,2 ± 8,6	69,7 ± 7,6	0,02
BMI (kg/m [2])		245 ± 4,2	25 ± 4,1	24,3 ± 4,3	NS (043)
Previous surgeries	Hysterectomy	16,6 % (26)	153% (17)	196% (9)	NS (064)
	Prolapse	13,4 % (21)	108 % (12)	196% (9)	NS (020)
	Incontinence	108 % (17)	9,9 % (11)	13% (6)	NS (058)
Associate conditions	Diabetes	7,6 % (12)	7,2 % (8)	8,7 % (4)	NS (075)
	Hypertension	31,2 % (49)	306 % (34)	326 % (15)	NS (081)
	Tobacco use	8,3 % (13)	9% (10)	6,5 % (3)	NS (076)
Prolapse	Uni-compartment	16,6% (26)	144% (16)	217% (10)	NS (026)
	Multi-compartment	83,4% (131)	856% (95)	783% (36)	
Surgical route	Vaginal	79,6 % (125)	784 % (87)	826 % (38)	NS (055)
	Laparoscopy	20,4 % (32)	216 % (24)	174 % (8)	
Anesthesia	General	92,4 % (145)	937 % (104)	89% (41)	NS (051)
	Regional	3,8 % (6)	3,6 % (4)	4,3 % (2)	
	Local/ Sedation	3,8 % (6)	6,5 % (3)	2,7 % (3)	
Concomitant procedure	**Hysterectomy**	**17,2 % (27)**	126 **%** [14]	283 **% (13)**	**0,02**
	Sub-urethral sling	20,4 % (32)	207 % (23)	196 % (9)	NS (087)

Table 2
Non eligibility to ambulatory surgery in overall population and in NEAS group.

Non eligibility criteria (%, nb)	Overall population n = 157	NEAS group n = 46
Lack of home support	14,6% (23)	500%
Home distance >100 km or 1 h	3,2% (5)	109%
Poor home conditions	0,6% (1)	2,2%
Associated comorbidity	6,4% (10)	217%
Associated procedure	1,3% (2)	4,3%
Refuse Ambulatory surgery	3,2% (5)	109%

Table 3
Ambulatory surgery rate.

Procedure	Overall population	EAS group
All procedures	58% (91/157)	82% (91/111)
Vaginal surgery	56% (70/125)	805% (70/87)
Laparoscopy	65,6% (21/32)	875% (21/24)
Concomitant hysterectomy	44,4% (12/27)	857% (12/14)
Concomitant sling	50% (16/32)	696% (16/23)

Table 4
Reasons for failure of AS in group EAS and sub group EAS failure.

Reason for failure (%, nb)	EAS n = 111	EAS Failure n = 20
Unsuccessful Trial of Void	11,7% [13] *1	65%
Post Operative Nausea/Vomiting	2,7% [3] *1	15%
Bleeding	0,9% (1)	5%
Sub-cutaneous emphysema	0,9% (1)	5%
Scheduling Error	1,8% [2] *2	10%
* Preventable Failures	4 (3,6%)	20%

and duration of surgery (Table 5). In multivariate analysis, end of surgery after 12 P M was the only remaining factor. OR = 5,3 (IC 95% 1,5–18,2) p = 0008.

EAS failure were considered as preventable in 4/20 (20%) (2 organizational mistakes, 1 Anesthesia/Analgesia protocol deviation, 1 PONV protocol deviation).

Re-admission, unplanned consultations and phone calls and post operative complications are comparable in EAS and NEAS group except for infection rate (mainly urinary tract) that is higher in NEAS group (Table 6).

Satisfaction rate regarding AS is 100% in EAS success group at day 1 and 92,3% (84/91) at 6 weeks; 89% would choose AS in the future. Regarding PGI-I at 6 weeks, 919% of EAS patients and 826% of NEAS patients felt “better” or “very much better” than before surgery.

Discussion

This study concerns AS in a population of surgically managed POP irrespective of surgical approach and technique. Previous publications reported results in selected populations of vaginal [14–16] or laparoscopic [17] surgery. Thus the optimal rate of AS for prolapse could not be estimated. 58% of our population could benefit of AS and this is consistent with previous estimations [14] but higher than others [4]. In France, AS rate for prolapse is low and Health Authorities asked for a change of paradigm so that AS become the reference in pelvic reconstructive surgery [11].

The AS rate could be higher by reducing non eligibility to AS and AS failures. Home distance is the major factor for non eligibility and can be bypassed by using hotel facilities [18]. Lack of home support is the second factor in our study related to the demographics of the population (widowness or husband disability). Refusal of AS is low in our study as reported by Hamid [14] and van der Waart [19]; patient information and reassurance is probably a key point for acceptance of AS.

In our study, the AS success rate is 824%. Sinhal [16] reported a higher rate in a population of vaginal mesh surgery (934%) but a significant number of patients (11%) were discharged with a Foley catheter at least for 1 day. Hill [15] reports a 95% success rate with 2,5% discharged with a catheter. Hamid [14] reports 881% of success.

TOV success is the main issue in AS of prolapse. 13/20 of our failures are related to TOV failure. In case of TOV failure, we chose to keep patient in the hospital, emptying bladder by intermittent catheterisation, while teaching them self catheterization. Most authors decided to discharge those patients with indwelling catheter that is removed later [3,15,16]; more patients then can be discharged the same day but have to be readmitted the following day. As there is no financial incentive, French patient prefer to stay overnight without a catheter and most of unsuccessful TOV patients (10/13) could be discharged the day after surgery.

Pre-operative hydration is paramount for post operative bladder filling [20] and some patients failed to void because of insufficient diuresis.

Concomitant sling surgery is known to affect bladder emptying after prolapse surgery [21], but did not reach significativity as a predictive factor of AS failure in our study.

Reducing EAS failure can be achieved by a precise management of micturition (pre-op hydration, concomitant sling placement, intermittent catheterisation protocol)), better planning and respect of anesthesia/analgesia/PONV protocols.

This study was the beginning of our experience in prolapse AS and we observed a preventable failure rate of 20% related to

Table 5
Univariate analysis of success and failure in EAS group.

Variable (mean ± SD or %, nb)		EAS success n = 91	EAS Failure n = 20	p
Age (years)		66 ± 8,5	65 ± 9,4	NS (066)
BMI (kg/m [2])		24 ± 4	24 ± 5	NS (075)
Prolapse procedure	Single	13,2% (12)	20% (4)	NS (043)
	Multiple	86,8% (79)	80% (16)	
Approach	Vaginal	76,9% (70)	80% (16)	NS (077)
	Laparoscopy	23,1% (21)	20% (4)	
Vaginal mesh surgery		70% (21)	80% (4)	NS (066)
Concomitant hysterectomy		13,2% (12)	10% (2)	NS (070)
Concomitant sling		17,6% (16)	35% (7)	NS (008)
Anesthesia/Analgesia/PONV protocol deviation		**14,3% (13)**	**35% (7)**	**0,03**
Duration of procedure (min)		**64 ± 39**	**83 ± 39**	**0,03**
End of procedure < 12 AM*		890**% (81)**	**65% (13)**	**0,007**
PO Morphine use		12,1% (11)	5% (1)	NS (035)

* Predictive factor in multivariate analysis: p = 0008.

Table 6
Health Care System use and complications at 6 weeks.

Variable (Mean ± SD, %, nb)	Global n = 157	EAS group n = 111	NEAS group n = 46	p
Length of stay (hours, mean /STD)	205 (2402)	14 (2638)	354 (17,45)	< 0,01
Health Care System use				
Hospital phone call	34,4% (54)	360% (40)	304% (14)	NS (050)
GP phone call	25,5% (40)	252% (28)	261% (12)	NS (091)
Unplanned consultation	8,9% (14)	7,2% (8)	13% (6)	NS (024)
Re-admission after discharge	3,2% (5)	3,6% (4)	2,2% (1)	NS (1)
Re-operation after discharge	0,6% (1)	0,8% (1)	0	NS
Complications				
Vaginal bleeding	1,3% (2)	0	4,3% (2)	NS (008)
Urinary retention > 24 h	2% (3)	1,8% (2)	2,2% (1)	NS (1)
Infection (UTI, wound)	7,6% (12)	**4,5% (5)**	152**% (7)**	**0,02**
Hematoma	3,8% (6)	3,6% (4)	4,3% (2)	NS (1)
Pain > 7 days	6,4% (10)	7,2% (8)	4,3% (2)	NS (072)
Haemorroids	2% (3)	1,8% (2)	2,2% (1)	NS (1)
Allergy	0,6% (1)	0	2,2% (1)	NS (029)
Total	23,6% (37)	189 **% (21)**	348 **% (16)**	**0,03**

scheduling mistakes or Anesthesia/Analgesia/PONV protocol deviation.

Post operative complication rates does not differ between EAS and NEAS groups except for infection rate that is higher in the NEAS group, mainly related to urinary tract infection. This is consistent with previous studies [22] and probably related to the early removal of bladder catheter and vaginal packing in the EAS group.

There have been a high post operative phone call rate to GP or to the institution. This have been seldomly reported in previous studies. Pre operative information could probably address this as most of them were related to re-assurance and not medical complications. There were few emergency consultation, re-admission or re-operation with no difference between the 2 groups. Although this is not a randomised study, AS does not seem to carry a higher complication rate than in patient surgery.

Patient satisfaction is high as reported by others [10,15,19]. Satisfaction is higher at day 1 than 6 weeks; this difference was reported by Lemos [10] who related dissatisfaction to pain control, post operative information and final outcome.

Conclusion

This is the first study reporting the feasability of AS in a population of surgically managed prolapse regardless surgical approach. Nearly 60% of patients were operated in an ambulatory setting and a higher rate is expected with an improvement in scheduling, anesthetic protocol observance and TOV management. There was no complications related to AS and patient satisfaction is high suggesting that patient acceptance is not an obstacle to AS.

Further randomized studies are needed to confirm acceptability and cost-utility of prolapse AS.

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Disclosure statement

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