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TITLE PAGE / ACKNOWLEDGEMENTS

Switching to single-use flexible ureteroscopes for stones management: financial impact and solutions to reduce the cost over a 5-year period

Authors

S. Dubnitskiy-Robin^{a,b,c}, B. Pradère^{d,e}, B. Faivre d'Arcier^d, S. Watt^f, T. Le Fol^g, F. Bruyère^{d,e}, E. Rusch^{a,c,e,h}, F. Monmousseau^{a,c}, S. Brunet-Houdard^{a,c}

^a Health-economic Evaluation Unit, University Hospital of Tours, France

^b Geriatric Unit, University Hospital of Tours, France

^c EA 7505 Education, Ethics, Health, University of Tours, France

^d Department of Urology, University Hospital of Tours, France

^e PRES Centre-Val de Loire, University of Tours, France

^f Pharmacy, University Hospital of Tours, France

^g Biomedical Unit, University Hospital of Tours, France

^h Medical Information Department, University Hospital of Tours, France

Corresponding author

Solène Brunet-Houdard, ueme@chu-tours.fr

CHRU de Tours, 2 bvd Tonnellé, 37000 Tours, France

+33.2.18.37.08.97

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Compliance with Ethical Standards

This article does not contain any studies with human participants or animals performed by any of the authors. The data used are either freely accessible on the Agency for Information on Hospital Care (AIHC) website (<https://www.scansante.fr>) or from the University Hospital of Tours hospital database (PMSI data).

This observational study on aggregated data does not require registration.

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Author contributions

BP initiated the research topic. BP and BFA brought their experience to value the key model parameters. SW and TLF performed the microcosting. ER provided PMSI data. SDR, FM and SBH performed the data collection, designed the model, performed the statistical analysis and wrote the initial manuscript in collaboration with BP. All authors have read and approved the final manuscript. SBH is the general guarantor.

Conflict of interest

The authors declare no relationship of interest likely to have affected the study methodology or results.

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MANUSCRIPT

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Abbreviations

AIHC: Agency for Information on Hospital Care; BI: Budget Impact; BIA: Budget Impact Analysis; HTA: Health Technology Assessment; SWL: extracorporeal shockwave lithotripsy; URS: ureteroscope; sURS: single-use ureteroscope; rURS: reusable ureteroscope

1 Introduction

Urolithiasis is a common disease which affects almost 1 in 11 people in the United States, and its prevalence has almost doubled over the past decades.¹ It is estimated that 10% of the population will experience urolithiasis in their lifetime.² Consequently many studies have already^{3,4} preempted the increase in the use of health care resources for this disease.⁵ Moreover, the advances and progress in mini-invasive surgery for stone treatment continue to raise the cost of care. Hence, urolithiasis management is recognized as an economic burden⁶, and its cost balance is now recognized as one of the important challenges in our health-care facilities.

Today, ureteroscopy is one of the first line treatments in urolithiasis management for most indications for renal stone surgeries.⁷⁻¹⁰ Until recently, ureteroscopies were only performed with reusable fiberoptic or digital ureteroscopes (rURS) which required a specific organization in health-care facilities in order to insure their reprocessing, maintenance and repair. Procedures could be canceled and rescheduled owing to the unavailability of rURS (broken or in repair).¹¹ Moreover, the fear of damaging rURS and their associated downtime could place constraints on the surgeon's technique, particularly in the case of complex urolithiasis.

Single-use digital ureteroscopes (sURS) are available since 2015, two of which are market leaders: the LithoVue™ (Boston Scientific) and the Pusen (Zhuhai Pusen Medical Technology Co.). sURS have been said to have many advantages, including the fact they no longer need to be reprocessed and maintained, that they are available at any time, allowing a higher number of procedures to be performed, and that they exhibit good maneuverability without the fear of breakage.¹²

The opportunity for a health-care facility to switch to sURS depends on its purchase price in comparison to the potential savings induced by no longer using rURS.^{13,14}

As presented in systematic literature reviews, studies compared the overall cost of rURS (purchase, reprocessing and repair) with the purchase cost of sURS.^{5,6,11,13,15-19} However, these studies estimated costs at one point in time, without considering the increase in urolithiasis incidence over time, and changes in the urolithiasis treatment strategy. Indeed, when ureteroscopy or SWL are potentially indicated there is a tendency to favor ureteroscopy,²⁰⁻²³ partly due to the recent change in clinical guidelines.^{8,24,25}

Budget Impact Analysis (BIA) is a more suitable method for estimating the financial consequences of adopting a new procedure. Two situations are usually compared: an environment in which the new procedure is implemented, and a counterfactual environment without the new procedure. The financial impact is estimated over a short-term period. The model takes the number of eligible patients and change in that number over time, the proportion of patients concerned by the new procedure, and the change in clinical practices, etc. into account in particular.

The aim of this study was to apply the BIA methodology to estimate the financial impact of switching to single-use flexible URS. This impact was estimated over a 5-

year period, from the French hospital's point of view considering both the costs and revenues related to urolithiasis management in health-care facilities.

2 Material and Methods

The BIA was conducted in accordance with the guidelines by The French National Authority for Health (HAS)²⁶ and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).²⁷ The budget impact model was created using Microsoft Excel 2010®.

2.1 Analytic framework

French hospitals are financed through activity-based tariffs. National tariffs with respect to diagnosis related groups (DRG) are based on the costs of resources used to produce the health-care services.

In the case of urolithiasis management, using sURS could change the production cost of ureteroscopy, without immediately changing the tariffs. Indeed, in France, the tariffs could be different from the costs (due to the type or brand of scope used and because the tariffs are based on previous cost data). Also, the financial balance, representing the difference between production costs and activity revenues, could be then affected by the use of sURS.

In the BIA, this financial balance was simulated in a first case where only rURS and SWL interventions were available in the hospital (as "current environment"). It was estimated according to two types of rURS: fiberoptic or digital.

Then, we estimated the financial balance in the case where the therapeutic arsenal included sURS, rURS and SWL (as "new environment"). In the base case analysis, we assumed that sURS completely replaced rURS.

The difference between the financial balances of the current and new environment represented the financial impact of switching to sURS. Two financial impacts were estimated based on whether the replaced rURS were digital or fiberoptic. The estimates were calculated per year and over 5 years (between 2018 and 2022). They were based on assumptions about the size of the target population and distribution of this population among the therapeutic strategies making up each environment.

2.2 Assumptions

The financial impact was estimated for a French public university hospital with an annual activity volume of approximately 200 stone patients requiring ureteroscopy or SWL procedures. This target population included French people over 18 years old. It was assumed to increase over time according to the rate of growth of the French population and the increased incidence of urolithiasis (Supplementary figure 1).

Each year, the expected number of patients treated by ureteroscopy (or SWL) was obtained by multiplying the target population by the proportion of URS (or SWL) procedures. Concerning ureteroscopy, its proportion was assumed to increase over time without exceeding 95%,^{6,28,29} in order to represent the expected change in urologists' practices.

Furthermore, the model considered assumptions regarding possible patient reallocation between ureteroscopy and SWL strategies. First, we assumed that ureteroscopy procedures could, in rare cases, be converted to SWL. This choice could be made so as not to cancel procedures when rURS was not available in the current environment due to damage for example. According to urology experts, the proportion of ureteroscopy to SWL conversions was estimated at 1% in the base case analysis.

Then, in the new environment, we also assumed that some SWL indications could be treated by ureteroscopy with an sURS, due to this device being more readily available than rURS. According to urology experts, this proportion was 100% and 25%, depending on whether SLW was performed with or without general anesthesia.

Finally, we assumed that the use of sURS could allow development of outpatient ureteroscopy. We defined, in the new environment, specific outpatient activity rates for the sURS (54%) and rURS (25%) strategies. Indeed, due to the acquisition of sURS in 2018 instead of rURS in our hospital, it was possible to determine the different outpatient activity rates.

2.3 Hospital costs and revenues

The revenue data related to hospital management of urolithiasis, corresponded to the tariffs applied to the relevant DRG in euros in 2018. Concerning the costs, we considered the cost of DRG for an SWL (with and without anesthesia) and for an inpatient or outpatient ureteroscopy procedure, the operating cost of rURS (fiberoptic or digital), and the negotiated price of sURS.

The costs of DRG were defined based on the French National Health Cost Scale for 2017 (corresponding to the average costs of hospital stays for each DRG from public hospitals for the year 2015). The consumer price index was used to adjust cost data for inflation.

The operating cost of a procedure performed with an rURS was calculated from local micro-costing. It included the negotiated price of an rURS (fiberoptic and digital), the costs of the reprocessing procedure by high level disinfection, the price of maintenance contracts including repair services (for rURS and reprocessing equipment) and the cost of quality control. That information allowed us to calculate an

amortized cost of rURS (fiberoptic and digital) considering the distribution of fixed costs depending on the number of rURS available in hospital and the number of ureteroscopies performed.

For the sURS, we considered the negotiated price of LithoVue™ (year 2018), the most expensive device at the time of the study. The value considered corresponded to the lower limit of the price range mentioned in a recent study.¹⁹ We assumed this price to undergo slight degression over the time period (-5%).

All the values used in the base case analysis are reported in supplementary table 1.

2.4 Sensitivity analysis

The financial impact of switching to sURS was re-estimated with other input parameter values (costs, tariffs, assumptions) to explore how the results varied from those of the base case analysis.

The different input parameter values were determined according to French national data from the Agency for Information on Hospital Care (AIHC), or were based on expert opinion (urologists and pharmacists), or as per a standard BIA, with a range of $\pm 10.0\%$ to $\pm 20.0\%$ around the base value. For the negotiated price of sURS, setting the bounds at $\pm 20.0\%$ around its central value made it possible to take into account the differences in the hospitals' bargaining chip, and the purchase price of other brands of sURS. The values used for the sensitivity analysis are reported in supplementary table 1.

First, we performed a univariate deterministic sensitivity analysis in order to measure the isolated influence of each input parameter on the financial impact. This allowed us to identify key-drivers.

Then, we implemented a multivariate analysis consisting in the successive and cumulative modification of one input parameter of the BIA model through several scenarios.

The first (scenario 1) corresponded to the base case analysis. Scenario 2 took into account the expected change in European clinical recommendations in favor of ureteroscopy in a context where the latest US recommendations have placed ureteroscopy as first-line treatment for urolithiasis.⁸ For this, we assumed that the practice of ureteroscopy would become more widespread more rapidly than assumed in the base case analysis.

The last three scenarios explored the consequences of concomitant implementation of several solutions to contain or reduce the financial impact. These solutions were identified from the results of the univariate sensitivity analysis, and sorted by decreasing probability of implementation according to expert opinion.

3 Results

3.1 Target population

The target population was the number of eligible patients treated by SWL or ureteroscopy. It was estimated at 196 patients in 2018 and 271 patients in 2022 (Figure 1).

The BI model allocated, in the current environment, 66.2% of the target population to the rURS strategy in 2018. This proportion increased over the period to reach 87.2% in 2022. In the new environment, 77.6% of population was allocated to the sURS strategy in 2018. In 2022, this proportion increased to 92% (Figure 1).

3.2 Hospital costs and revenues

The revenues and costs related to the different strategies in the current and new environments (considering the comparison of sURS to fiberoptic rURS) are shown in supplementary table 2 and table 3.

Due to the target population growth (Figure 1), revenues increased steadily in each environment. Revenues from ureteroscopy procedures were higher in the new environment than in the current environment. Indeed, in the new environment, we assumed that a proportion of SWL could be converted into ureteroscopy due to the availability of sURS. Moreover, the tariff for the ureteroscopy DRG was higher than SWL tariff.

The overall costs of ureteroscopy (rURS and sURS) were higher and progressed further in the new environment than in the current environment due to the acquisition of sURS and the increase in the number of ureteroscopy procedures. Note that the same trends were found when sURS was compared to digital rURS (See supplementary table 4 and table 5).

3.3 Financial Impact

In case of comparison with a fiberoptic rURS, the annual financial impact of switching completely to sURS was estimated at €145,305 in 2018 and €179,848 in 2022 (Table 1). As the costs were higher than the revenues in each environment, this financial impact corresponded to an additional net cost for the hospital. The same progression was observed with the digital rURS as reference (Supplementary table 6).

The cumulative financial impacts over 5 years were estimated in case of fiberoptic and digital rURS comparisons respectively at €807,824 (€702 by patient) and €649,677 (€564 by patient). The financial impact of switching from digital rURS to

sURS was lower due to the higher market price of the digital rURS compared to the fiberoptic rURS.

3.4 Univariate Sensitivity Analysis

The specific effect of each input parameter on the financial impact is presented in figure 2 (for the comparison with a fiberoptic rURS) and in supplementary figure 2 (for the comparison with a digital rURS).

When the sURS was compared with the fiberoptic rURS (Figure 2), the proportion of sURS among ureteroscopy procedures had the highest impact on the result. With a rate of 20% instead of 100%, the cumulative financial impact would be divided by 3.1 over 5 years (€259,080 instead of €807,824). With regard to the negotiated price of LithoVue™, a 20% discount would reduce the cumulative 5-year financial impact by 24.8%. Moreover, the target population portion treated for urolithiasis in a public hospital (as urolithiasis rate) had a significant impact on the results. Indeed, if the urolithiasis rate increased by 20%, the financial impact over 5 years would increase by about 22.6%. Finally, if the rate of SWL without anesthesia converted to sURS increased from 25% to 50%, the cumulative financial impact would be estimated at €885,724 which would represent a 9.6% increase.

3.5 Multivariate Sensitivity Analysis

Conversely to the base case analysis, scenario 2 considered the impact of the new clinical recommendations through an increase in ureteroscopy compared to SWL. As a result, the 5-year financial impact would increase from €807,824 to €846,874 when compared to fiberoptic rURS and from €649,677 to €686,372 when compared to digital rURS (Figure 3).

In addition to scenario 2, scenario 3 modeled a 20% discount on the purchase price of sURS. This level had an important effect since the 5-year financial impact would decrease by 24.9% (€635,840) and 31.2% (€472,366) compared to fiberoptic and digital rURS respectively.

Scenario 4, in addition to scenario 3, represented a 20% increase in the rate of outpatient activity for the sURS strategy, and would imply a 5.2% and 6.3% decrease in the financial impact.

Finally, scenario 5 assumed a 20% decrease in the production costs of outpatient ureteroscopy, and would imply a 5-year financial impact of €402,727 and €242,225 compared to fiberoptic and digital rURS respectively. The decrease in production costs could illustrate an organizational change due to sURS use in clinical practice.

4 Comment

The aim of this study was to assess the financial impact of sURS use to treat urolithiasis, for a public university hospital with an activity volume of approximately 200 ureteroscopy or SWL procedures per year. The 5-year financial impact was estimated at €649,677 (digital rURS as a comparator), and at €807,824 (fiberoptic rURS as a comparator). We showed that the concomitant implementation of different solutions could reduce this impact: negotiating the purchase price of sURS, developing outpatient care and reducing the production costs of the ureteroscopy procedure.

Our results help further knowledge by offering the first BIA on sURS use. Previous studies offered a comparative cost analysis^{11,13,17-19} or a cost-benefit analysis¹⁴ without making multiyear financial projections or assumptions about the increase in urolithiasis incidence over time.

Moreover, the original feature of this study was to consider possible patient reallocation between ureteroscopy and SWL strategies due to the availability of sURS. The introduction of this hypothesis into the model made it possible to better address the reality of practices and their evolution in urology. We implemented a multivariate analysis in the aim of identifying possible solutions in order to contain or decrease the expected financial impact. Finally, in a context where single-use devices are developing in many medical specialties and where efforts are being made to streamline allocation of resources, the question of adopting and financing costly technological innovations in health-care facilities is major. The BIA appears to be a relevant decision-making tool. In future research, we will show how this model can be used to define optimal distribution between sURS and rURS in a hybrid strategy.

Nonetheless, our study had several limitations. Our model used data describing the management of urolithiasis in French public hospitals where patients are insured. Its applicability to private or foreign hospitals may therefore be limited. Nevertheless, by modifying the parameter values in the sensitivity analysis, the differences between these hospitals were taken into account. It also considered the price of maintenance contracts for rURS and reprocessing equipment. Therefore, it did not apply directly to hospitals that do not have maintenance contracts, and therefore bear the full cost of repairs, the amount of which may otherwise be higher than the price of maintenance contracts. Moreover, the financial impact of switching to sURS could be overestimated because the model did not take broader organizational changes into account (reallocation of staff previously dedicated to the reprocessing of rURS, additional revenues due to the increase in the availability of hospital beds). A multi-criteria analysis as a Health Technology Assessment (HTA) should be considered in

the future to explore the technological, medical, infectious risk, environmental, organizational, economic and strategic impacts of the use of sURS within health-care facilities.

5 Conclusion

This study estimated the financial impact over a 5-year period using a budget impact model. We considered the increase in urolithiasis incidence, and change in practices due to the availability of sURS in a health-care facility. We showed that the high cost of switching completely to sURS could be significantly reduced by the concomitant adoption of different solutions, such as negotiation of the purchase price of sURS, development of outpatient activity and reduction in the production costs of ureteroscopy procedures. On the basis of these results, the BIA could help practicing urologists and their health-care facilities to determine the place they could give to single-use devices in their therapeutic arsenal.

FIGURES

Figure 1 Distribution of the target population between the different strategies in the base case analysis, for each environment

Figure 2 Univariate sensitivity analysis if the comparator is a fiberoptic rURS (in € 2018)

Figure 3 Multivariate sensitivity analysis if the comparator is either a fiberoptic or a digital rURS

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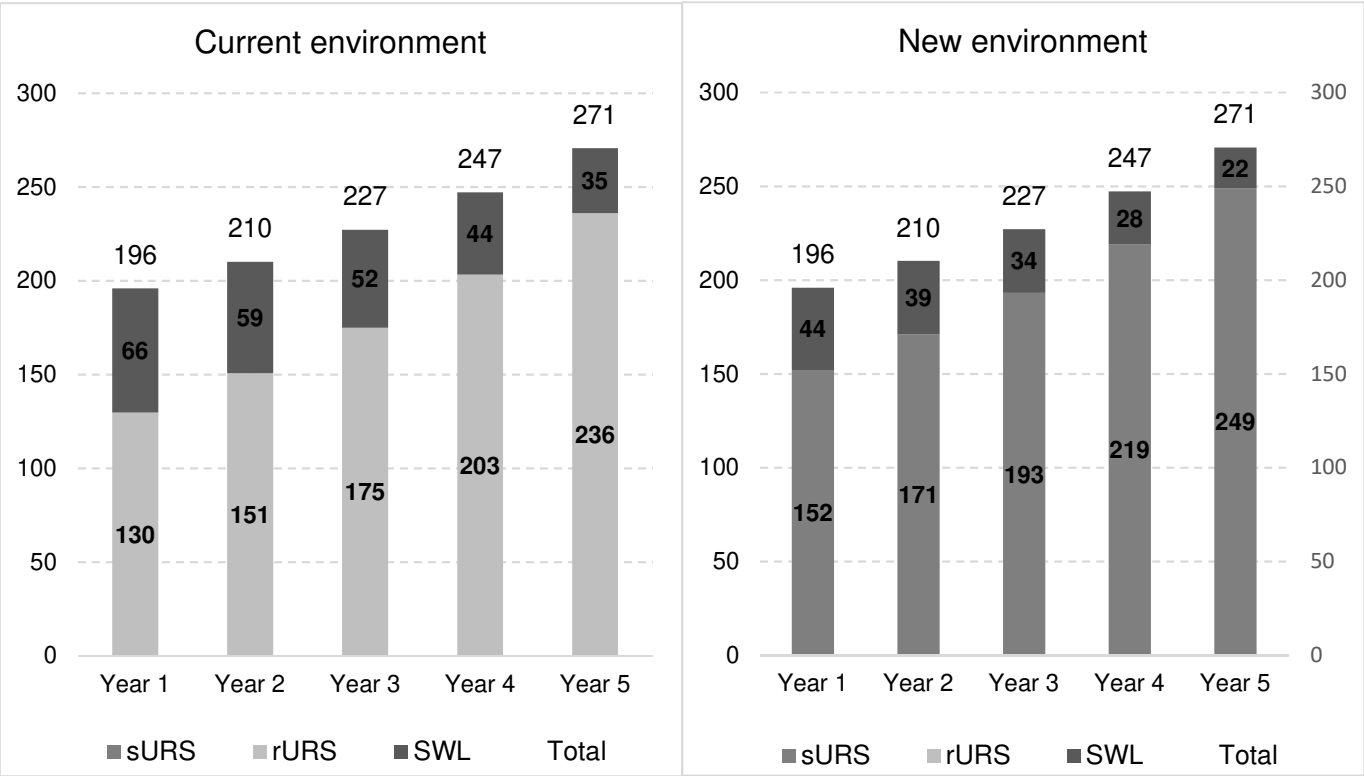
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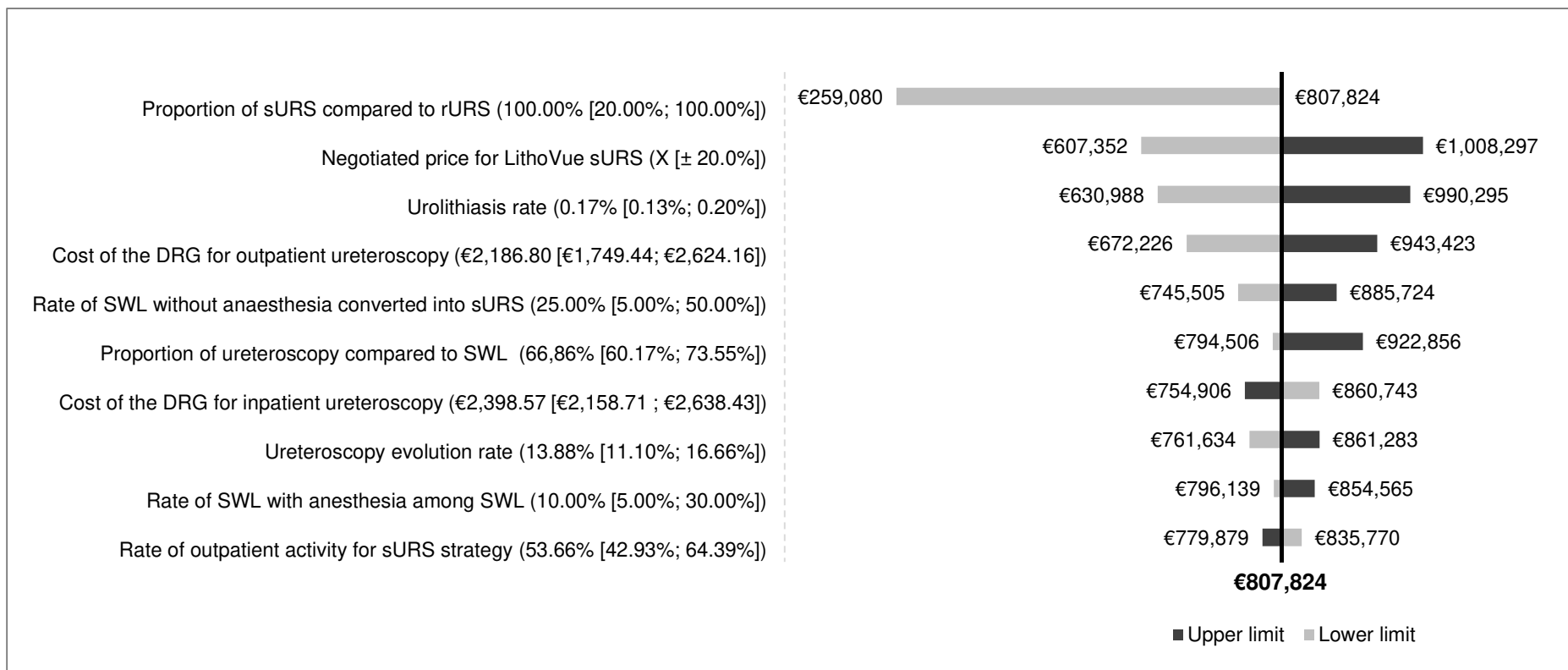
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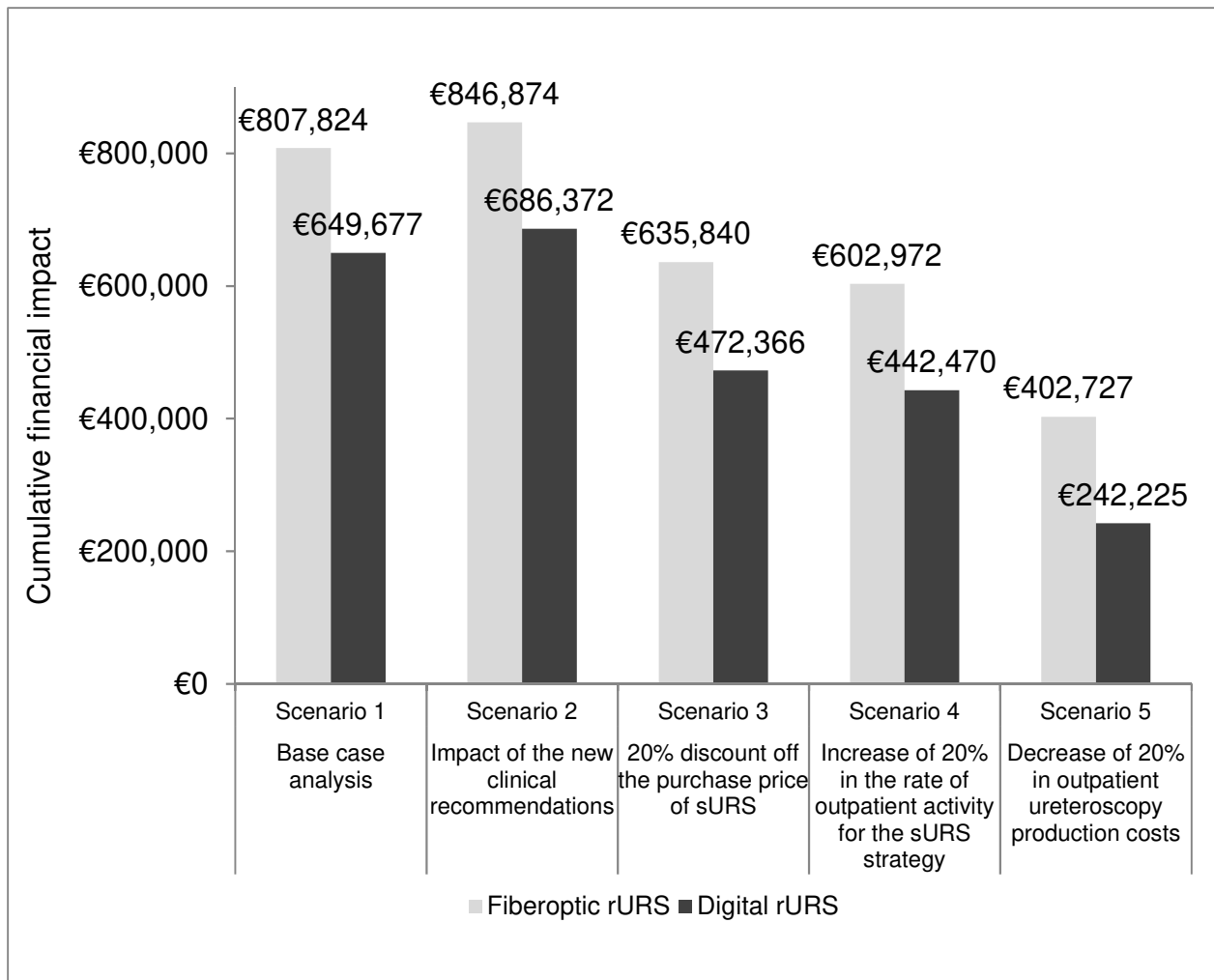
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FIGURES





Note: When the negotiated price for LithoVue sURS was equal to its base case value, the financial impact was €807,824. In the sensitivity analysis, when this price was 20% cheaper (lower limit), the financial impact was €607,352. When this price was 20% more expensive (upper limit), the financial impact was €1,008,297.



Note: sURS: single-use ureteroscope; rURS: reusable ureteroscope; SWL: extracorporeal shockwave lithotripsy

TABLES

Table 1 Financial impact of switching completely to sURS compared to fiberoptic rURS (in € 2018)

		Year 1	Year 2	Year 3	Year 4	Year 5
Financial impact	Total	€145,305	€152,890	€161,675	€168,105	€179,848
	per patient	€742	€727	€712	€680	€665
Cumulative financial impact	Total	€145,305	€298,196	€459,871	€627,976	€807,824
	per patient	€742	€734	€726	€713	€702