

Italian endourological panorama: results from a national survey

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Introduction The purpose of this survey was to explore the dissemination of flexible ureteroscopy (fURS), shockwave lithotripsy (SWL) and percutaneous nephrolithotomy (PCNL) in the Italian urological community and to know the real availability of the complex endourological armamentarium all over the country.

Materials and methods An online questionnaire characterizing the case volume/year of upper urinary tract stone treatment and the availability of flexible ureteroscopes (FUs) armamentarium was sent to all urological Italian centers.

Results The survey was sent to 294 urological centers and 146 responded (49.7%). The case volume/year of fURS was the following: <20 cases in 20 centers (13.7%); 20–50 cases in 40 centers (27.4%), >50– <100 cases in 55 centers (37.8%) and >100 cases in 28 centers (19.2%). The case volume/year of SWL was the following: <50 cases in 18 centers (12.3%); >50– <200 cases in 56 centers (36.4%) and >200 cases in 35 centers (24%). In 37 centers (25.3%) SWL was not utilized at all. The case volume/year of PCNL was the following: <10 cases in 20 centers (14%); >10– <30 cases in 55 centers (30%), >30– < 50 cases in 33 centers (23%), >50– <100 cases in 13 centers (9%) and >100 procedures in 2 centers (1%). However, 24 centers (16%) did not perform any PCNL procedure.

Four centers (3%) did not have any FU at the moment of the survey. The availability of FUs was as follows: 1 FU in 21 (14%) centers, 2 FUs in 61 (42%) centers, 3 FUs in 29 (20%) centers, 4 FUs in 13 (9%) centers and ≥5 FUs in 16 (9%) centers. Only 82 (56%) centers had all of their FUs in working condition.

Conclusions This survey succeeded in providing a complete overview on the Italian endourological panorama.

Key Words: endourology ↔ survey ↔ urolithiasis ↔ flexible ureteroscopes
↔ shockwave lithotripsy ↔ percutaneous nephrolithotomy

INTRODUCTION

Urolithiasis is an endemic disease whose prevalence and incidence are rapidly increasing. It reaches its peak between the third and fourth decade, with a lifetime risk of stone formation exceeding 11% in men and 7% in women [1].

In a recent 5-year update on the changes in treatment of upper urinary tract stone disease in England, it has been demonstrated that the retrograde endoscopic treatment of kidney stones has en-

countered a dramatic growth (103% increase since 2009–2010) [2].

Despite this increased popularity of flexible ureteroscopy (fURS) among the urological community [3], no information exists on the availability of flexible ureteroscopes (FUs) in different urological centers. The aim of this survey was to explore the dissemination of fURS, shockwave lithotripsy (SWL) and percutaneous nephrolithotomy (PCNL) in the Italian urological community and to know the real availability of the complex endourological

armamentarium (FUs and laser machines) all over the country.

MATERIAL AND METHODS

In January 2016, an online questionnaire characterizing the case volume per year of upper urinary tract stone treatment and the availability of FU armamentarium was sent to all urological Italian centers through e-mail. The addresses of these centers were obtained from the database of the Italian Ministry of Health. The survey instrument contained 7 questions; the questions were multiple choice, while one of them had free text response (see Appendix).

The survey was conducted using the web-based Survey-Monkey system (Palo Alto, CA). Responders were invited to participate through an initial email from our Department with a brief description of the survey and a hyperlink of the survey. A second reminder email was sent two weeks later and the survey remained open for one month.

RESULTS

The survey was sent to 294 urological centers and 146 responded (49.7%). The results are reported in Figure 1.

Case volume per year of stone treatment

The case volume per year of fURS was the following: <20 cases in 20 centers (13.7%); between 20–50 cases in 40 centers (27.4%), between 50–100 cases in 55 centers (37.8%) and >100 cases in 28 centers (19.2%).

The case volume per year of SWL was the following: <50 cases in 18 centers (12.3%); between 50–100 cases in 34 centers (23.3%), between 100–200 cases in 22 centers (15.1%) and >200 cases in 35 centers (24%). However, in 37 centers (25.3%) SWL was not utilized at all.

The case volume per year of PCNL was the following: <10 cases in 20 centers (14%); between 10–20 cases in 31 centers (21%), between 20–30 cases in 24 centers (9%), between 30–40 cases in 13 centers (9%), between 40–50 cases in 20 centers (14%), between 50–100 cases in 13 centers (9%) and more than 100 procedures in 2 centers (1%). However, twenty-four centers (16%) did not perform any PCNL procedure.

Flexible ureteroscopes availability per center (during the time of survey)

Four centers (3%) did not have any FU at the moment of the survey. The availability of FUs was

as follows: One FU in 21 (14%) centers, two FUs in 61 (42%) centers, three FUs in 29 (20%) centers, four FUs in 13 (9%) centers and \geq five FUs in 16 (9%) centers. Only 82 (56%) centers had all of their FUs in working condition. Of the remaining centers, 29 had 20–40% of their scopes sent for repair, 22 had half of their scopes sent for repair, 4 had 60–70% of their scopes sent for repair and the remaining 3 had all of their scopes sent for repair. Digital FUs were available only in 59 (40%) centers. Among those centers, 40 (68%), had just one digital FU.

Laser machines

The availability of laser machines was as follows: 120w laser machine in 6 (4%) centers, 100w laser machine in 20 (14%) centers, 30w in 58 (40%) centers, 20w in 42 (28.7%) centers and 10w in 11 (7%) centers.

Six departments had no laser machines available. Among them, 2 only used fURS for diagnostic purposes in cases of upper tract urothelial carcinoma (UTUC), while 4 were in the process of acquisition of the machine. Three other centers did not know the wattage of their laser.

DISCUSSION

Meaning of our survey

Treatment options for patients with kidney stones is mainly based on three procedures: PCNL, fURS and SWL. In the past few years the combination of refinements in the endourological armamentarium, the downsizing of FUs, the advent of digital technology and the introduction of holmium laser lithotripters has ameliorated the outcomes and safety of fURS [4], making its use increasingly attractive and widespread among the urological community and rendering it able to compete with traditional SWL and PCNL, even in special and complicated clinical circumstances [5]. Despite recent population-level evidence demonstrating increasing utilization of fURS [2, 6, 7], no worldwide information exists on FU availability among urological centers including in Italy.

The present survey was conducted to better understand the Italian endourological scenario in order to figure out the effective dissemination of the different stone treatment procedures and to know the availability of endourological instrumentation for successfully performing fURS. Our survey results show an annual case volume of 20–50 cases in 27.4% centers and 50–100 cases in 37.8% centers. However, while 13.7% centers performed <20 cases, 19.7% performed >100 cases annually showing a wide variability in its uptake and use.

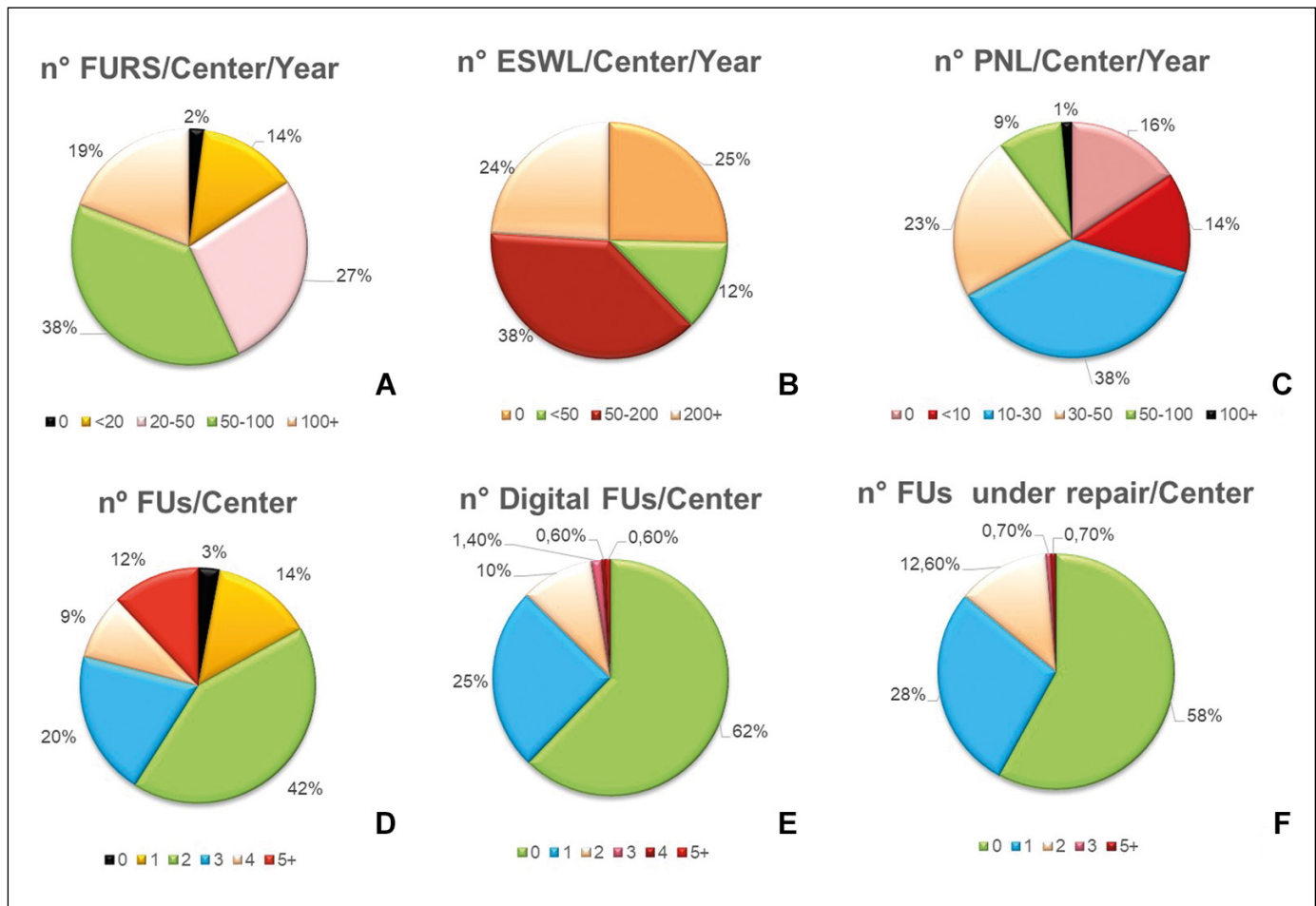


Figure 1. Dissemination of fURS, SWL and PCNL (A, B, C) and FUs availability (D, E, F) in the Italian urological community.

Regarding endourological variability in practice with SWL, 24% centers performed >200 cases annually, while 25.3% did not perform any SWL procedure. This last result could be explained by the lack of SWL lithotripters in those centers. The aforementioned findings parallel with the data reported by Heers et al. in which it has been showed that in England although SWL is still performed more than URS, it has plateaued, while fURS has encountered a dramatic growth of 103% since 2009/2010 [2]. This is likely from a reduced stone free rate (SFR) with SWL when compared to fURS with lesser number of retreatments necessary. In fact, a meta-analysis of the effectiveness of SWL, fURS and PCNL revealed a better SFR with PCNL than with SWL (RR 2.04) and fURS than SWL (RR 1.31) at 3-month follow-up, in patients with renal stones [8]. Secondly, it has also to be taken into account the fact that in some countries such as Italy, SWL's reimbursement by public health systems according to DRGs is much less remunerative than that it was in the past, and inferior to both fURS and PCNL.

Another finding extrapolated from our study was the case volume of PCNL per year performed in centers involved in this survey. In fact, in the majority of centers the case volume of PCNL was very low or even absent. This is in line with the widespread feeling among the Italian urological community that PCNL is still considered complex and potentially burdened by major complications implying a longer learning curve and more endourological skills to train [9]. Moreover, the extensive dissemination of ultrasound has changed the clinical scenario of kidney stones, allowing their diagnosis at earlier stages when they are relatively small and, consequently, expanding the pool of patients who may benefit from fURS rather than from PCNL. In addition, according to this survey, 14% and 42% of centers had 1 or 2 FUs in their departments respectively and, at the time of the survey, the majority of this centers had one FU which was damaged and/or under repair. Despite technological advancements in endourology, the durability of reusable FUs still remains a major concern potentially adding to the cost of its repair and maintenance [10].

Availability of back-up fURS

An important concept for centers performing fURS is the potential availability of only one scope during surgery which could risk a postponement if a 2nd look was necessary due to a lack of sufficient endourological armamentarium. This would be a disappointing result for both the surgeon and patient which also carries ethical implications. Furthermore, this would also have an impact on the waiting list times which is usually already quite long due to an overwhelming request for oncological surgeries. This is an important message drawn from the survey for centers performing these procedures where at least two functioning and sterilized instruments should be available in the operating room (OR) in order to ensure the safe completion of the procedure without any unforeseen delays. Notably, when a hospital can not afford to acquire and maintain 2 traditional reusable FUs, the availability of a last generation disposable flexible scope might be the solution to prevent this undesired situation to happen [11, 12]. Moreover, as our survey shows a long repair time for FUs ranging between 2–3 months, our suggestion is always to ask to the manufacturers for repair-exchange contract in order to have all the equipment available at all times. In addition, it is noteworthy that the digital FUs spread is very limited in Italian centers, considering that 62% of departments have not this facility, 25% of them just one digital FU and only 13% of centers have between 2–5 digital FUs. This merits further discussion since Somani et al. demonstrated that an advantage of digital FU is the reduction by 20% of OR time when compared to fiber optic scopes, this might be an argumentation in favor of acquisition also of more costly digital scopes rather than only the less expensive fiber optic counterpart. Conversely, it should be highlighted that no difference was detected in terms of SFR between these scopes [13].

Choice of fURS and laser generators

Due to the actual economical constraint of our country and to the fact that in some situations the maneuverability of fiber optic FUs is better than digital [14], we believe that a digital FU is not mandatory to perform a good stone surgery. Conversely, the highly superior vision guaranteed by digital FU, in our opinion, is essential when the endoscopic conservative treatment of the upper tract urothelial carcinoma (UTUC) is performed.

Our survey also showed that the supply of laser generators is quite good across the country with only 6 out of 146 departments devoid of them. This is a key point: laser machine is the essence of fURS. Apart

from the electrohydraulic generator whose safety profile is not accepted any more, no other lithotripter can be used efficiently through a modern FU. Twenty-six centers (17.6%) were lucky enough to have a high power generator (120–100 w). Although interestingly, among them 5 had only one FU. An explanation of that could be that laser prostate surgery is also performed at those centers. Otherwise the acquisition of such a costly machine is not completely meaningful: money saving with the acquisition of a cheaper low power laser generator could have allowed these centers to acquire a more complete endoscopic equipment. High power lasers offer a wider and more precise combination of settings especially in terms of pulse rate regardless the fiber's diameter but they are not a must have device for lithotripsy, which rarely requires more than 20 watts. As a matter of fact, after reading the comments throughout the survey, Italian endourologists did not complain significantly about laser generators, but mostly about the availability of endoscopic equipment (FUs and disposable accessories).

Implications of our survey and suggestions for improvements

What clearly emerges from this survey is that what limits the national dissemination of fURS is the combination of cost in acquisition and maintenance of the delicate FUs and disposable armamentarium, and the related reimbursement by the national public health care system that, for instance, is very low, especially when compared to the one of PCNL (roughly 50% less). This is not without ethical implication because such a huge discrepancy in reimbursement might be the reason to select a procedure based on the remuneration rather than the indication for it. Last but not least, also all involved urological companies should cooperate in limiting costs of both acquisition and maintenance of the delicate and costly endourological armamentarium so that all dedicated endourologists may obtain all necessary technology and equipment to cure their patients according to the best healthcare guidelines. Good modern day endourology can not be carried out without adequate armamentarium.

As such, according to all of the findings extrapolated from this survey, one important issue might come into question on whether we need to concentrate stone and UTUC endoscopic treatment in dedicated referral centers where a major availability in terms of armamentarium and experience is present.

As matter of fact, given the increasing worldwide prevalence [15] and the economic impact of nephrolithiasis [16], standardization and centralization of the procedures could have the potentiality to improve outcomes and decrease expenditures also

in Italy, according to the American model of regionalization [17].

Truthfully, in some countries we are increasingly witnessing the implementation of the concept of specialized tertiary referral centers where a dedicated endourology team is present and it has access to a full range of endourology equipment and instrumentation. This shift could be explained by improved outcomes and need of decreasing costs that result from standardization of practice patterns [18]. In support of this, the suggestion that the regionalization of certain procedures that are technically more complex in tertiary referral and specialized centers, may improve the overall quality of the health care system [18]. Moreover, this translates into better results and reduced morbidities and complications related to this surgery [19]. As a matter of fact, it has been shown, for example, that the results of a semirigid ureteroscopy correlate with the case volume, demonstrating that high-volume centers achieved significantly better treatment outcomes than did low-volume centers [19].

This is one of the reasons that might explain why nearly one-half of physician care in the United States is not based on best practices [20] and that at least 98,000 Americans die of a medical error each year [21]. Of course the process of regionalization of medicine is not easy and it should imply an official strategy that only Ministry of Health can decide. But it is clear that nowadays we are witnessing a gradual shifting from "pay-for-performance" to "pay for value" system. All findings raised by this survey seem to corroborate this concept and might be a first step toward creating a standard equation that measures outcomes and rewards hospitals for delivering value, i.e. high quality outcome and a satisfied patient at the lowest possible cost [22].

Limitations of our survey

However, certain limitations that constrain the implication of this survey must be acknowledged. Due to the general lack of evidence of surveys, answers

obtained from responders serve more as descriptive findings and a general mirror of the endourological situation in Italy, than evidence of appropriate statistical analysis of the data reported. Anyway, to our best knowledge, this is the first survey that describes the endourological situation in an entire country, describing the dissemination of the endourological procedures and flexible ureteroscopic instrumentation. In addition, it is interesting to note is the response rate of our survey that was 49.7%, higher than previous endourology surveys [3, 23], with therefore a good influence of generalizability of our results. All that being said, this survey might help the public health system and in general the endourological community, to figure out that, for the aforementioned reasons, the regionalization of endourological procedures to referral tertiary centers could be a viable alternative instead of dissipating the economical resources in the territory in several low volume centers without cost-effectiveness.

CONCLUSIONS

This survey succeeded in providing a complete overview on the Italian endourological situation in terms of availability of all the required endourological instrumentation.

Italian endourologist appeared to be keen to embrace endourology in general and flexible ureteroscopy (fURS) in particular, but costs of acquisition and maintenance of endourological endoscopic equipment could condition and slow down its capillary dissemination across the country.

CONFLICTS OF INTEREST

Proietti S., Somani B., Pietropaolo A., Saitta G., Rodriguez-Socarras M., Rosso M., Bellinzoni P., Gaboardi F.: declare that they have no conflict of interest. Giusti G. declares that he is consultant for Coloplast, Rocamed, Olympus, Lumenis, Boston Scientific, Karl Storz, Cook Medical.

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