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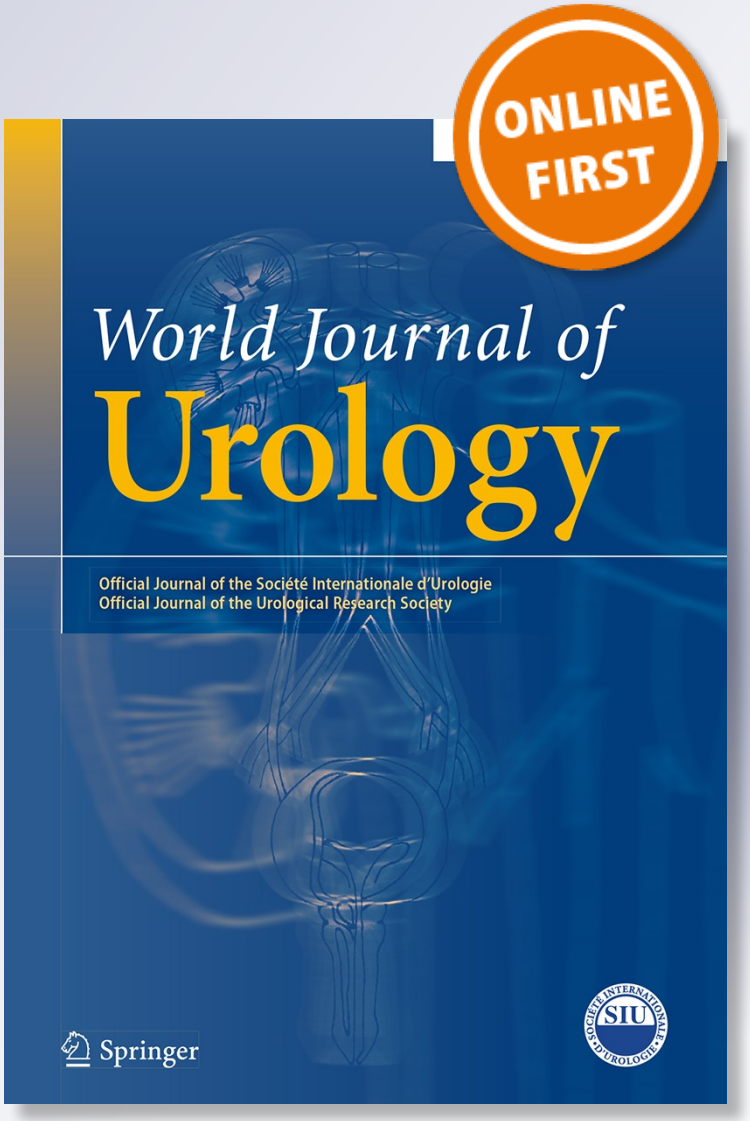

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ORIGINAL ARTICLE

Use of XenX™, the latest ureteric occlusion device with guide wire utility: results from a prospective multicentric comparative study

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Abstract
Purpose This is a prospective multicentric comparative study evaluating the performance of XenX—a new dual-purpose device for the prevention of stone fragments migration during ureteroscopic lithotripsy (URS).
Methods Between March 2014 and January 2015, 41 patients undertaking URS + XenX were matched with 41 patients undergoing standard URS. Patients included had unilateral ureteric stone(s) of 0.5–1.5 cm in maximum size. Demographics, complication rates and surgical outcomes were recorded for comparison. A Likert-like 5-grade scoring system was used for surgeons' evaluation of XenX properties. Cost analysis was performed by comparing weighted mean costs of the relevant procedures.
Results Patients' characteristics between the two groups were comparable. Lasering time was longer for XenX group (13.59 vs. 5.17 min; $p = 0.0001$) whilst use of basket and need of JJ stent insertion was more frequent in control group (19.5 vs. 97.6 %; $p = 0.0001$ and 22 vs. 35 %; $p = 0.001$, respectively). Intra-operative SFR was significantly higher for XenX group (100 vs. 85.4 %; $p = 0.0001$), but not at 4-week follow-up, after ancillary procedures were needed in 17.1 % of the control group. Surgeons' evaluations for XenX were suboptimal for "Ease of Basketing" (2/5) and "Advancement of double J stent" (3/5). The use of XenX increased costs of procedures, but spared the costs associated to ancillary procedures and stent removals.
Conclusions XenX confirmed to be a safe and effective device especially for the treatment of upper ureteric tract stones; moreover, XenX may reduce the risk for the need of auxiliary procedures and for the insertion of a JJ stent.

Keywords Ureteric stone · Preventive retropulsion device · New technology · Endoscopic lithotripsy

Introduction

Migration of stone fragments in the kidney during endoscopic lithotripsy of ureteric stones is an adverse event which is variably influenced by a number of factors such as stone size, stone number and site, experience of the operator, type of lithotripter used, facilities and devices available.

Retropulsion rates of stones or clinically significant fragments requiring ancillary procedures have been reported ranging from 2 to 40 %, with highest rates related to ureteric stones in proximal ureter and of more than 10 mm in size [1–5].

Several devices for the prevention of stone migration have been introduced in the last years: Stone Cone™ and NTrap™ are among the most popular, followed more recently by Accordion™ and BackStop™. Other devices

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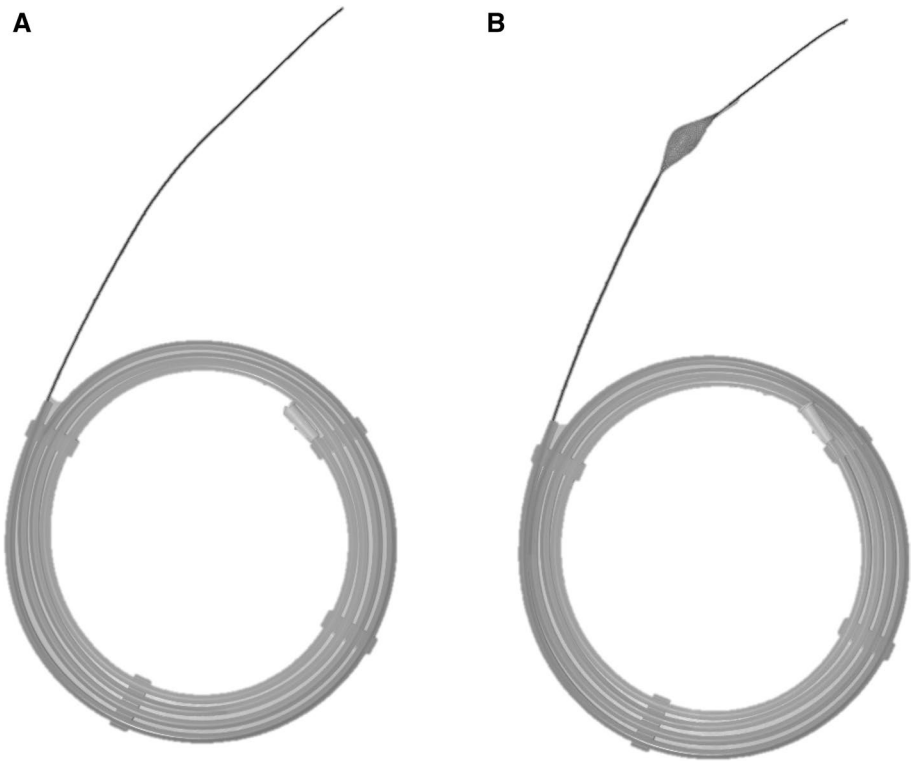

Fig. 1 XenX undeployed (**a**) and deployed (**b**)

include stone baskets such Escape™ and Lithocatch™, suction devices such as Lithovac™ or even balloon catheters as the Passport™ [6, 7].

The latest device introduced in the market is XenX™ (produced by Xenolith and marketed by Rocamed), a dual-purpose product designed as a safety guide wire with a built-in stone retention capability that prevents retrograde stone migration during ureteroscopic lithotripsy. It consists in a floppy hydrophilic tip of 15 cm to past easily the stone and in a 5-cm expandable braided Nitinol mesh able to occlude the ureteric lumen up to 12 mm in diameter and retain stone fragments up to 1 mm in size (see Figs. 1, 2). XenX has been tested in an ex vivo study and in a small cohort study [8, 9]; herein, we present the first prospective multicentric comparative study to evaluate the performance of XenX in preventing stone fragments migration during ureteroscopic lithotripsy.

Materials and methods

Study design (stage 2a according to the IDEAL model for the evaluation of surgical innovation [10]) was agreed in April 2014 among the 9 centres involved. The case group (group I) consisted of patients undertaking semirigid ureteroscopy and laser fragmentation (URS) the aid of XenX, whilst in the control group (group II) patients were treated with standard URS without any anti-retropulsion device. Forty-five patients undergoing URS with XenX were recruited between March 2014 and January 2015; sample size depended on number of devices provided by the manufacturer. During the same period, 81 patients underwent standard URS in 3 of the centres involved and constituted the pool of the control group subjects. No randomization was performed to allocate patients in the relevant groups. Inclusion and exclusion criteria are listed in Table 1.

Endpoints of the study included:

1. *Safety and efficacy of XenX in comparison with control group* variables in observation were surgical and clinical characteristics (lasering time, overall operative time, use of basket, JJ stent insertion, hospital stay); intra- and post (at 4 week)-operative complication rates according to Satava and Clavien–Dindo classification systems, respectively; intra- and post (at 4 weeks)-operative stone-free rates (SFR). Stone-free condition was defined as residual fragments $\leq$2 mm and was assessed intra-operatively with retrograde pyelogram, and at 4-week follow-up by ultrasound kidney–ureter–bladder (US KUB), X-ray KUB and/or computerised tomography (CT) KUB according to centres' protocols. Decision for JJ stent insertion was based on risk of post-operative complications for significant residual fragments or extensive manipulation of the urinary tract (e.g. oedema of the ureteric orifice, clots). Ancillary procedures were recorded, including flexible URS

Fig. 2 Detail of floppy tip and deployed braid

(fURS) performed in the same session in the case of stone migration into the kidney.

2. *Ease of use of XenX* a Likert-like 5-grade scoring system (1 = very bad; 5 = very good) was used by surgeons for subjective evaluation of XenX properties, such as pushability, ease of deployment, full expansion and co-optation to ureter walls, kink resistance, stone retention capabilities, device retrieval, ease of stenting, device radiopacity and ease of basketing
3. *Cost-effectiveness of XenX* cost analysis was performed by comparing weighted mean costs of the procedures in each group.

Local ethical committee approval has been obtained where needed; otherwise, the recruitment of patients was conducted in agreement with the Declaration of Helsinki.

The chi-square test was used when comparing categorical and ordinal variables between the two groups; the independent-samples *t* test was used when testing mean differences for continuous variables. A p value <0.05 was applied to reject the null hypothesis; all tests were two-tailed. SPSS version 17 has been used for the statistical analysis.

Results

In 41 patients, XenX was successfully used; in further 4 patients (8.9 %), surgeons removed the device because of failure of its deployment system.

Forty-one patients of the control group were randomly selected; same proportion of patients with distal and proximal stones was kept for a matched-pair analysis.

Demographics, complication rates and surgical outcomes are summarized in Table 2. Combination of X-ray and US KUB was the prevalent imaging test used at 4-week follow-up, used in 22 and 21 cases of groups I and II, respectively. Other tests included X-ray KUB alone in 6 and 19 cases, US KUB alone in 5 and 1 patients and CT KUB in 8 and 0 cases, respectively.

Endpoints' outcomes

Safety and efficacy of XenX

There was a significant longer difference in the lasering time for XenX group (13.59 vs. 5.17 min; $p = 0.0001$) whilst use of basket and need of JJ stent insertion was significantly more frequent in the control group (19.5 vs. 97.6 %; $p = 0.0001$ and 22 vs. 35 %; $p = 0.001$, respectively).

Neither intra- nor post-operative complications were observed in group I. There were two grade II Clavien–Dindo complications (fever) in group II; however, no statistic difference was found between the two groups.

Intra-operative SFR was significantly in favour of XenX group (100 vs. 85.4 %; $p = 0.0001$); however, at 4-week follow-up, no more difference was recorded (100 vs. 90.2 %; $p = 0.054$).

Ancillary procedures were needed in 7 patients (17 %) out of the control group and all consisted in fURS performed in the same session. All these cases involved ureteric stones in the proximal tract. Ureteric access sheaths were used in all fURS cases which may have contributed in the higher proportion of JJ stent insertion in this group.

Table 1 Inclusion and exclusion criteria

Inclusion criteria
1. Clinical indication for treatment of ureteral stone by ureteroscopic lithotripsy
2. Ureteral stone, single or multiple, 0.5–1.5 cm in maximum diameter
3. Diagnosis confirmed at CT KUB
4. Age >18 years
5. Able and willing to return to treatment centre for follow-up visits
6. Subject is able and agrees to sign the informed consent form
Exclusion criteria
1. Known ureteral stricture
2. Intrarenal calculi on the ipsilateral side
3. Fever, active kidney infection or evidence of sepsis
4. Pregnancy
5. Patient already recruited in another clinical study
6. Stone larger than 15 mm
7. Stone in the uretero-pelvic junction

Table 2 Demographics and surgical outcomes

	Group I (XenX)	Group I (control)	*p*
Pts number	41	41	
Gender			
Male	25	23	n.s.
Female	16	18	n.s.
Pts age (SD)	49.06 (±14.8)	49.36 (±12.68)	n.s.
Mean stone burden mm (SD)	9.9 (±2.8)	10.24 (±2.5)	n.s.
Stone site			
Proximal	33	33	
Distal	8	8	
Mean operative time (SD)	38.73 (± 15.8)	46.15 (± 18.3)	n.s.
Mean lasering time (SD)	12.3 (± 8)	5.1 (± 1.5)	0.0001
Intra-operative complication %	0	0	
Use of basket %	19.5	97.6	0.0001
Need of JJ stent %	22	35	0.001
Hospital stay (SD)	2.08 (± 1)	1.95 (± 1)	n.s.
SFR			
Intra-operative	100	85.4	0.017
4 weeks	100	90.2	n.s.
Auxiliary procedures	0	17.1	0.006

The four patients (9.8 %) of control group non-stone free were deemed for observation because residual fragments were asymptomatic and <4 mm in diameter.

Ease of use of XenX

Median operators' evaluations for XenX were "Good" (4 out of 5) for "Pushability", "Ease of deployment", "Full expansion and cooptation to ureter walls", "Kink resistance", "Stone retention capabilities", "Device retrieval", "Device radiopacity". Poorer scores were recorded for "Ease of Basketing" (2/5) and "Ease of stenting" (3/5).

Cost-effectiveness

XenX is marketed in UK for a price of 150 GBP per unit; however, adjusted cost in our series was 164 GBP by including the 4 devices that could not be used because of deployment system failure. Adjusted costs of the disposable materials are shown in Table 3; the disposables listed are among those most commonly used across the centres and varied according to the technique adopted (i.e. with or without the use of XenX). Costs and quantity of other disposables normally used (laser fibres, irrigation/lines, contrast media, lubrication, etc.) were consistent across the centres so they were not reported because did not have any impact in the cost evaluation.

Overall, average cost per procedure in group I was 196.16 GBP versus 162.5 GBP computed for group II.

However, in this list the costs of the ancillary procedures, of the drugs for the relief of stent-related symptoms and of the stent removal have not been accounted as they vary considerably across the centres involved. All these additional costs were accounted mainly in control group where ancillary procedures and insertion of JJ stents were more frequent.

Discussion

In the last years, several devices have been introduced in the market to increase the effectiveness of ureteroscopy and endoscopic lithotripsy for the treatment of ureteric stones.

Even though in some series the use of endoscopic lithotripsy with Holmium-YAG laser has increased the stone-free rates [3, 11], the risk of stone fragments migration into the kidney is still present, especially in the case of stones in the upper ureter [1–5].

Fragment retention devices have been introduced to prevent stone and fragments migration into the kidney which causes the need for additional manoeuvres and/or ancillary procedures and involves longer time for the patients to be successfully treated with potentially higher costs associated.

Table 3 Evaluation of costs

	Price (GBP)	Price (GBP) adjusted per average units/case	
		Group I (XenX)	Group II (control)
N-Circle™ basket 3.0 CH	131	25.56 (8/41)	127.07 (40/41)
JJ stent 5 ch	30	6.60 (9/41)	10.50 (14/41)
Sensor™ guide wire	25	0 (0/41)	25 (41/41)
XenX	150	164 (45/41)	0 (0/41)
TOTAL (GBP)		196.16	162.5

Wire-, balloon- and gel-based devices are currently available in the market: the ideal retention device should be able to prevent migration of millimetric fragments, effectively collapse the lumen also in case of dilated ureters, be easy and safe to use and be cost-effective [6, 7].

Main characteristics of wire-based retention devices are summarized in Table 4.

Stone Cone™ and N-Trap™ have been the devices of this kind more extensively tested: the former consists of a stainless steel wire wound with a strand of Nitinol on the tip which deploys producing a spiral shaped cone, preventing the migration of fragments >1.5 mm for ureters dilated up to 1 cm in diameter. Results from 5 studies are available in literature showing stone-free rates ranging from 97.5 to 100 %, according to the different definitions of stone-free adopted by the relevant authors [12–16].

The N-Trap™ is a 3 Fr occlusion device deploying a 7-mm umbrella-shaped mesh made of tight woven Nitinol™ wires; the mesh is designed to retain fragments of 1 mm in the central part of the umbrella and of 2 mm in the outer sides. Most significant results have been published in a recent meta-analysis [17] including 2 randomized controlled trials [18, 19] and 1 case–control study [20]: stone-free rate for N-Trap™ ranged from 83 to 100 %, which was significantly higher than controls also at the pooled analysis [OR = 3.08, 95 % CI (1.45–6.53)].

XenX™ has been introduced in the market very recently: it is the first dual-purpose device combining guide wire function with anti-retropulsion ability. The deployable braid can occlude a ureter dilated up to a diameter of 12 mm, and the woven Nitinol mesh is design to prevent stone fragments even less than 1 mm. The braid is built in a reinforced stainless steel sheath of 150 cm in length, 0.040-in in calibre, and with a 15-cm floppy hydrophilic distal tip to ease insertion of ureteric catheters/stents.

In an ex vivo study with porcine models, XenX showed to prevent stone migration the most compared to other anti-retropulsive devices, including Stone Cone and N-Trap [8]. Main advantages reported for XenX consisted in the ability to retain smaller fragments (up to 1 mm in diameter) and to occlude a more dilated ureter (up to 12 mm).

A preliminary clinical experience with XenX was more recently published by Montanari et al. [9]: in their report, 15 patients underwent URS with XenX for ureteric stone of 8.5 mm in mean size; 14 were stone-free in the kidney at discharge, but all patients were deemed stone-free at 4-week follow-up by performing a CT KUB. In 27 % of the cases, the authors experienced difficulties in pushability and kink resistance; no intra-operative complications were recorded. Limitation of this study was the lack of a control group.

Our study is the first prospective, multicentric study comparing XenX with controls.

XenX was confirmed to be a safe device as no complications were recorded intra- and post-operatively.

The 100 % of SFR makes XenX's efficacy at least comparable to the other anti-retropulsive devices.

Most of the time, the device showed to be easy to use. Nevertheless, some limitations were recorded and involved: (1) possible inability to deploy the braid; this event occurred in 8.9 % of the cases and it is the main issue for the manufacturer to address. (2) Use of baskets along XenX may be somehow awkward; however, the fine fragmentation/dusting which is possible to achieve thanks to its highly effective anti-retropulsive ability limits the need to retrieve fragments. In our series, basketing was deemed necessary only in 19.5 % of the cases. Moreover, based on our experience, XenX should not be used as a basket device because of potential significant bruising of ureteral mucosa. (3) Stenting is possible only with stents

Table 4 Main characteristics of wire-based retention devices

	N-trap™	Stone cone™	Accordion™	XenX™
Main components	Expandable Nitinol "umbrella" mesh	Hydrophilic tip Expandable stainless steel + nitinol cone	Hydrophilic tip Expandable film/plug	Hydrophilic tip Expandable stainless steel + nitinol braid
Outer diameter	3 Fr	3 Fr	3 Fr	3 Fr
Max expansion width (mm)	7 mm	7–10 mm	7–10 mm	10–12 mm
Mesh tightness	1 (central) mm 2 (external) mm	1–2 mm	1–2 mm	<1 mm

with 0.038-in of inner calibre; unfortunately, most of the current stents in the market are designed to pass through a ≥0.035 in guide wire. On the other side, in our cohort of XenX patients, the insertion of a stent was needed only in 22 % of the patients.

These latter 2 statements were confirmed by the matched-pair analysis of the intra-operative outcomes: when comparing group I with group II, significant differences were recorded with respect to the lasering time, the need of basketing and of JJ stent insertion (12.3 min vs. 5.1 min, $p = 0.0001$; 19.5 vs. 97.6 %, $p = 0.0001$; 22 vs. 35 %, $p = 0.001$, respectively). This may imply that with the aid of XenX surgeons are able to perform a more accurate and finer fragmentation of stones, with minimal manipulation of the ureters; as a consequence, most cases may result in highly effective and uncomplicated URS which prevents the need for the insertion of a JJ stent. Even though this may be seen as a minor step of the procedure from the surgical point of view, the presence of a JJ stent can affect significantly the quality of life of patients [21].

Most importantly, there was a significant difference in favours of XenX group when analysing intra-operative SFRs (100 vs. 85.4 %, $p = 0.0001$). This difference disappeared at the 4-week follow-up (100 vs. 90.2 %, $p = 0.054$) at the cost of 7 auxiliary procedures needed in group II which corresponded to a fURS in all the cases. All the fURS were performed in the same sessions; stones migrated in the collecting systems were treated locally, and fragments were not extracted, and hence, the reason of the different SFR reported intra- and post-operatively. Interestingly, all these cases involved stones in the upper tract of the ureters, which may imply a more specific indication of XenX for stones in this location.

With respect to cost-effectiveness analysis, the use of XenX increases the cost per procedure with respect to standard URS. On the other side, control group was exposed to a significant higher number of ancillary procedures; also, the higher number of JJ stent insertions involves extra costs for drugs to relieve stent-related symptoms and for the stent removal. We were unable to precisely evaluate costs on these regards especially when it came to evaluate the additional costs of fURS in the same session: prizes for the sterilization of the flexible ureteroscopes, costs of the device per usage (which depends on the agreements in place with manufacturers), specific durability of the devices in each centre varied significantly across the centres involved; also, days off work for stent-related symptoms were not recorded and reimbursement fees for the stent removals differed notably.

This study has some limitations: small size of groups and lack or randomization have contributed to the introduction of sampling and selection bias.

There was heterogeneity with respect to the imaging tests used at the follow-up which has contributed in the introduction of an assessment bias.

We were unable to report the exact dilatation (if any) of the ureter at the time of the procedure; however, in none of the case, XenX was unable to occlude completely the ureter.

Finally, cost-effectiveness analysis was limited by the low number of cases included and by the inability to determinate the additional costs for ancillary procedures and post-operative care (pain relief, stent removal and work days off).

Conclusion

XenX is a safe and effective device for the treatment of ureteric stones; its utility is likely to be more marked in the case of stones of the upper tract of the ureter, especially in those centres where flexible URS and/or laser technology are not available.

Significant improvement is needed from the manufacturer to improve ease of use of the device and to optimize the dual-purpose utility; on the other side, XenX may reduce the risk for the need of auxiliary procedures which contributes to increase costs related to the stone-clearance. XenX may reduce also the need of the insertion of a JJ stent, preventing bothersome symptoms for patients and cutting extra costs.

Authors' contribution F. Sanguedolce involved in protocol/project development, data collection, management, data analysis and manuscript writing/editing. E. Montanari and O. Traxer involved in protocol/project development and manuscript writing/editing. M. Alvarez-Maestro, N. Macchione and S. Hruby involved in protocol/project development and data collection. A. Papatsoris involved in protocol/project development, data collection and manuscript editing. P. Kallidonis, P. Honeck and L. Villa involved in protocol/project development and data collection. F. Greco: protocol/project development, data collection and manuscript writing/editing.

Compliance with ethical standards

Conflict of interest Prof E. Montanari is Olympus stone advisory board; Prof O. Traxer is consultant for Olympus, Coloplast, Rocamed and Boston Sc.; Dr. F. Sanguedolce received grants from Xenolith in 2013 in support of registration fees for the EAU Annual Meeting and the World Congress of Endourology.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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