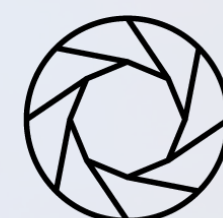


EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY OR URETER STENT AFTER KIDNEY COLIC? A REAL-WORLD DATA ANALYSIS OF SHORT-TERM AND LONG-TERM OUTCOMES

Manfred Stapff, MD, PhD, TriNetX, Inc., Cambridge, MA, USA



TriNetX

RESEARCH OBJECTIVE:

The intense digitalization of healthcare with electronic medical records (EMR) enable analyses of real-world data (RWD) which were not possible years ago, thus allowing the scientific evaluation of therapeutic interventions which are difficult to study in double blind randomized clinical trials (RCT). For example, extracorporeal shockwave lithotripsy (ESWL) and ureteroscopy with stent (URS) are two main methods of treating ureteral stones, but it is unclear which treatment is more effective and safer.¹ Our aim was to compare the short-term and long-term clinical outcome of ESWL and URS using RWD .

1) Drake T et.al. What are the Benefits and Harms of Ureteroscopy Compared with Shock-wave Lithotripsy in the Treatment of Upper Ureteral Stones? A Systematic Review. Eur Urol. 2017 Nov;72(5):772-786. doi: 10.1016/j.eururo.2017.04.016

STUDY DESIGN:

We performed a retrospective observational study using the “Analytics” subset of TriNetX, a global federated research network with access to statistics on EMR from 66 million patients in 53 large healthcare organizations predominately in the USA. Diagnoses have been coded by ICD10 (ureter stones: N20.1), procedures by CPT, and laboratory values by LOINC. The date of ESWL (CPT 50590) or URS (CPT 52356) within 30 days of a renal colic (N23) were used as index event (IE). Short-term complications (bleeding, inflammation, infection, pain, ER visit) were observed within day 1 to 30, long-term outcomes (defined like short term complications plus hospitalization or urinary tract obstruction) between day 90 and 365 after IE.

POPULATION STUDIED:

Among 48 million patients in the TriNetX “Analytics” network we found 223,466 patients with a diagnosis of ureter stones, of which 36,257 (16%) had a documented renal colic in their EMR. 2,499 (7%) patients underwent one of the two procedures of interest within 1 month after a colic, i.e. 1,771 (71%) URS (mean age 49.4 yrs, 55% male) and 728 (29%) ESWL (46.8 yrs, 63% male).

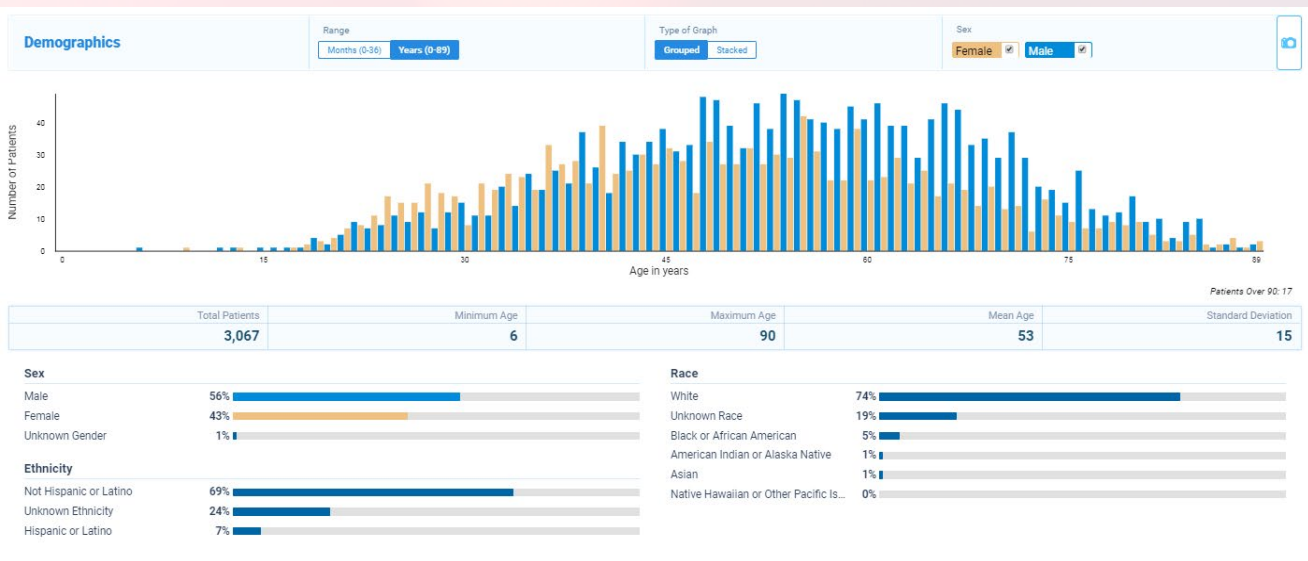


Figure 3. Demographics of the population studied

PRINCIPAL FINDINGS:

Short-term outcome:

The overall 30-day complication rate was 25.1% for URS and 25.0% for ESWL. URS had a higher rate of inflammation/infection, especially in women (12.1% vs 7.5%, p=0.043).

Long-term outcome:

29.2% of patients in the URS group experienced at least one adverse long-term outcome, compared to 29.4% with ESWL. In both genders, URS had a significantly lower rate of pain than ESWL (7.4% vs 11.7%, p=0.0007), but a somewhat higher rate of ER visits or hospitalizations (20.6% vs 19.2%, p=0.65), potentially confounded by the need for stent removal. Women experienced slightly less inflammation or infection after URS compared to ESWL (11.1% vs 14.7%).

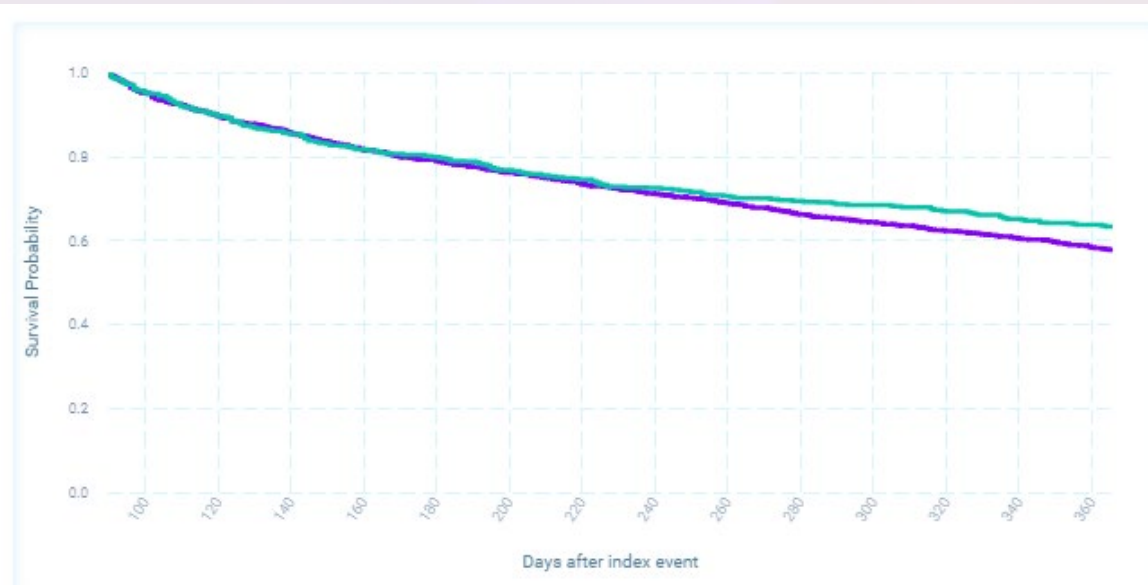


Figure 4. Kaplan-Meier curves: any complication up to one year post procedure (both genders); purple = URS, green = ESWL

Table 1. Summary of main findings (“URS = ureteroscopy with stent; ESWL = extracorporeal shockwave lithotripsy)
* = p<0.05 for short term observation URS vs ESWL;
** = p<0.05 for long term observation URS vs ESWL

	URS	ESWL	URS	ESWL
	Short term		Long term	
Any complication, both genders	25.1%	25.0%	29.2%	29.4%
Infection, women only *	12.1%	7.5%	11.1%	14.7%
Infection, men only	5.9%	5.1%	4.2%	3.9%
Pain, both genders **	11.4%	12.4%	7.4%	11.7%
ER visit, both genders	14.0%	12.6%	20.6%	19.2%
Hematuria, both genders	6.3%	6.6%	4.8%	5.8%



What are the Benefits and Harms of Ureteroscopy Compared with Shock-wave Lithotripsy in the Treatment of Upper Ureteral Stones? A Systematic Review

Tamsin Drake^a, Nikolaos Grivas^{b,c}, Saeed Dabestani^d, Thomas Knoll^e, Thomas Lam^{f,g}, Steven MacLennan^h, Ales Petrlikⁱ, Andreas Skolarikos^j, Michael Straub^k, Christian Tuerk^l, Cathy Yuhong Yuan^m, Kemal Saricaⁿ

^aDepartment of Urology, Royal Bournemouth Hospital, Bournemouth, UK; ^bDepartment of Urology, Hatzikosta General Hospital, Ioannina, Greece; ^cDepartment of Urology, The Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands; ^dDepartment of Urology, Södra University Hospital, Malmö, Sweden; ^eDepartment of Urology, Sinsinglen-Boeligen Medical Center, University of Tübingen, Sinsinglen, Germany; ^fDepartment of Urology, Aberdeen Royal Infirmary, Aberdeen, Scotland; ^gAcademic Urology Unit, University of Aberdeen, Aberdeen, Scotland; ^hDepartment of Urology, Charles University, First Faculty of Medicine, Prague, Czech Republic; ⁱDepartment of Urology, Hospital Ceske Budějovice, Czech Republic; ^jSecond Department of Urology, Sismanoglio Hospital, Athens Medical School, Athens, Greece; ^kDepartment of Urology, Technical University Munich, Munich, Germany; ^lDepartment of Urology, Hospital of the Sisters of Charity, Vienna, Austria; ^mDivision of Gastroenterology & Cochrane UCPD Group, Department of Medicine, Health Sciences Centre, McMaster University, Hamilton, Canada; ⁿDepartment of Urology, Dr. Luigi Kidar Research and Teaching Hospital, Istanbul, Turkey

Figure 1. Published meta analysis. Source: Literature (1)

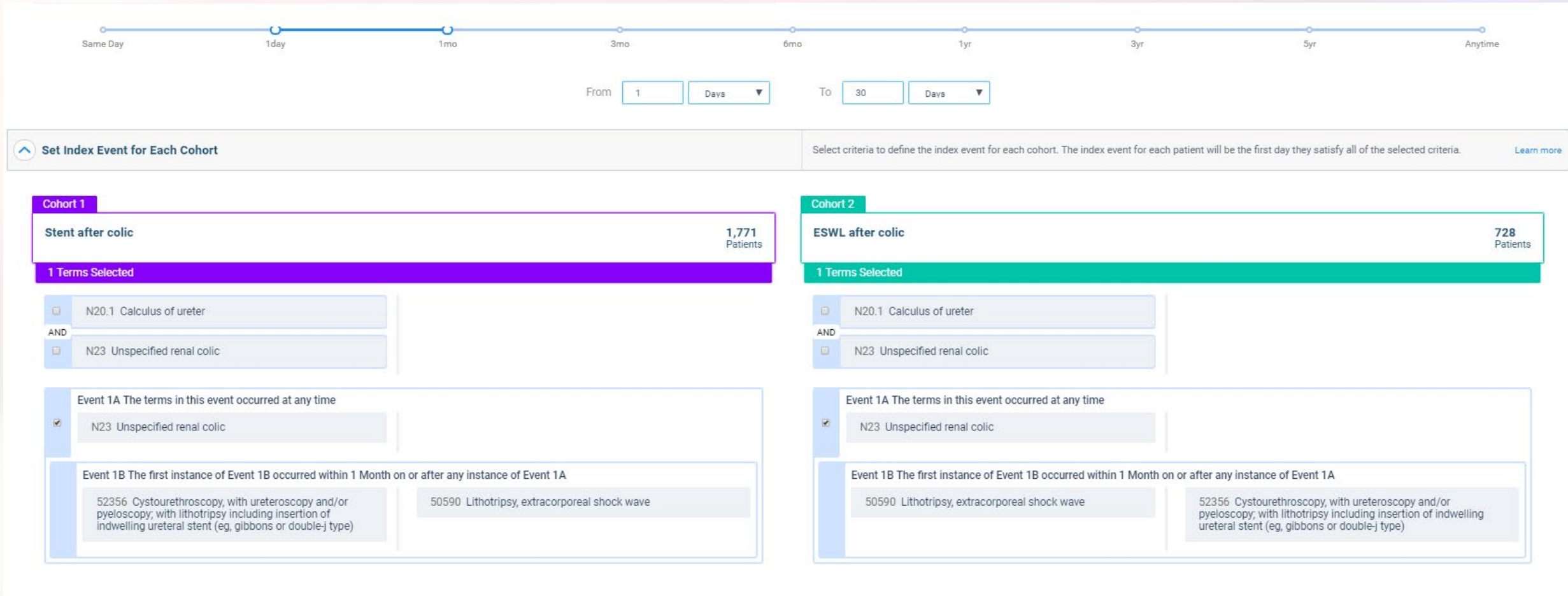


Figure 2. Screenshot of the cohort definitions. Example: short term observation window (TriNetX Analytics online platform)

IMPLICATIONS FOR POLICY OR PRACTICE:

- EMR allow the evaluation of outcomes after therapeutic interventions outside the experimental setting of RCT.
- RWD analyses should become more influential in treatment guidelines or patient specific decision making.