

Effect of Evidence Based Guidelines on Health Outcomes among Patients Undergoing Extracorporeal Shock Waves Lithotripsy for Urolithiasis

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Abstract

Background: Extracorporeal shock wave lithotripsy is an effective non-invasive method for managing urinary tract calculi. The application of evidence based guidelines in combination with extracorporeal shock wave lithotripsy in dealing with urolithiasis patient can provide simple and more effective measure to improve clinical outcomes and reduce risk of stone recurrence. **Aim of the study:** Was to evaluate effect of evidence-based guidelines on health outcomes among patients undergoing extracorporeal shock waves lithotripsy for urolithiasis. **Design:** A quasi experimental study design was utilized. **Setting:** The study was carried out at the Urology Department in Benha University Hospital. **Subjects:** A purposive sample of 80 conscious patients undergoing extracorporeal shock wave lithotripsy for urolithiasis randomly divided into control group (n=40) & intervention group (n=40). **Tools of data collection:** Two tools were used, **Tool I:** A structured interview questionnaire involving socio-demographic characteristics, medical and surgical history data and knowledge assessment questionnaire, **Tool II:** Extracorporeal shock wave lithotripsy health outcomes assessment tool. **Results:** Patients' knowledge level regarding Extracorporeal shock wave lithotripsy was significantly higher among intervention group than control group after implementing guidelines. As well as there was a significant statistical differences between both groups regarding pain score in term of pain improvement to be finally (1.28 ± 1.6 & 4.10 ± 2.2 , respectively). Also, there was significantly lower incidence of complications as well as higher quality of life score among intervention group than control group at p value ≤ 0.05 after three months of guidelines implementation. **Conclusion:** Implementation of evidence-based guidelines was effective in improving patients' health outcomes with lower pain score, lower incidence of complications and a positive impact on patients' quality of life among intervention group than control group. In the light of significantly improved knowledge level among intervention group compared to control group. **Recommendations:** Continuous evaluation of patients' knowledge regarding post extracorporeal shock wave lithotripsy instructions periodically to determine the effect of guidelines implementation during follow up periods.

Key words: Evidence based guidelines, extracorporeal shock waves lithotripsy, patients' health outcomes, urolithiasis.

Introduction:

Nephrolithiasis ranks third among urological diseases in terms of prevalence, making up about 15% of cases globally. The continued increase in the incidence of nephrolithiasis is most probably due to changes

in eating habits (high protein, sodium, and sugar diets) and lifestyle (reduced physical activity). Some 80% of all kidney stones cases are oxalate urolithiasis, which is also characterized by the highest risk of recurrence. Frequent relapses of

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nephrolithiasis contribute to severe complications and high treatment costs. (Wigner & Saluk-Bijak, 2022).

Newly developed minimally invasive procedures have displaced open stone surgery. Extracorporeal Shock Wave Lithotripsy (ESWL), Percutaneous Nephrolithotomy (PCNL), and flexible ureteroscopy are the currently used therapeutic methods. To date, guidelines have confirmed ESWL as the method of first choice for small and mid-sized urinary calculi. However, currently urologists and patients are more critical about ESWL when considering the best treatment for a stone (Yuri et al., 2020).

Extracorporeal shock wave lithotripsy (ESWL) has been used widely due to its relatively high efficacy and non-invasive nature for treating urinary stones. ESWL has a satisfactory treatment effect, particularly for ureteral stones <1 cm. ESWL can replace invasive treatment using a ureteroscope, and the European Association of Urology (EAU) guidelines suggest ESWL as the first treatment option for stones <1 cm (Yoon et al., 2021).

Patients with urolithiasis had a poor Quality of Life (QoL) in domains of health. Therefore, patients treated with ESWL are at risk for several complications which may have tremendous negative impact on physical and psychological conditions that lead to lowering the quality of life. Moreover, all the studies demonstrate decreased QoL in stone patients. Further, other chronic medical illnesses in stone patients significantly worsen QoL (Gvozdić et al., 2020).

Evidence-based practice is now widely recognized as the key to improving healthcare quality and patient outcomes. Evidence-based nursing practice (utilizing best evidence as basis of nursing practice) seem quite different, an increasing number of research studies to promote health outcomes. Therefore, lifestyles modification related to dietary habits, fluid

intake, weight reduction, physical activity, follow up and compliance with therapeutic regimen are particularly an improvement strategy for self-management for renal stones (Abdelwahab et al., 2021).

Role of nurse include patient preparations for procedure, instructions, and precautions to be followed throughout the procedure and discharge plan to prevent recurrence of the stones, all of that should be planed individually to meet every patient needs and diagnosis. Nursing management and education in ESWL unit is very important. Several studies indicated that patient's knowledge about urolithiasis disease and ESWL procedure was inadequate and there is a need for further studies about it (Ibrahim et al., 2017).

Significance of the study

Urolithiasis is a global problem affecting all geographical regions throughout the globe. Annual approximate prevalence is 3-5%. Urolithiasis tends to be recurrent in most of the renal calculi patients. Recurrence rates of renal stone are approximately 10% year, 50% over a period of 5-10 years and 75% over 20 years period (Gadzhiev et al., 2021). According to annual statistical report for Benha university hospital (2020) that 500 patients admitted to urology department for urological surgery which ESWL cases performed were approximating 100 cases for first times. ESWL is an effective treatment for kidney stones smaller than 20 mm in diameter (Maldonado-Valadez et al., 2022).

Aim of the study

The study was aimed to evaluate effect of evidence-based guidelines on health outcomes among patients undergoing extracorporeal shock waves lithotripsy for urolithiasis.

Research hypothesis

To achieve the aim of this study the following research hypotheses would be formulated:

- H1:** Patients' knowledge level would be significantly higher among intervention group than control group after implementing evidence-based guidelines.
- H2:** Patients' pain score would be significantly lower among intervention group than control group after implementing evidence-based guidelines.
- H3:** Patients' incidence of complications would be significantly lower among intervention group than control group after implementing evidence-based guidelines.
- H4:** Patients' quality of life would be significantly improved among intervention group than control group after implementing evidence-based guidelines.

Subject and methods

Research design:

A Quasi-experimental research design was utilized to conduct this study.

Research settings:

This study was conducted at the Urology Department at Benha University Hospital that is located at 4th floor in ESWL unit, which equipped with Extracorporeal lithotripter (**PiezoLith 3000**) machine type.

Study subjects:

A total purposive sample of 80 conscious adult patients undergoing ESWL for urolithiasis were assigned to current study, where the sample size was estimated based on the report of benha university hospital census, 2020 for admission in urology department, and divided randomly into 40 (**Intervention group**) receiving evidence base guidelines, 40 (**Control group**) receiving routine care included Adult conscious patients from both sexes and willing to participate in

study, patient who aged (20-60 years), patient who with ureter and renal stones, and patient who is the first time undergoing Extracorporeal Shock Wave Lithotripsy (ESWL).

Exclusion criteria:

- Patient who had a cute urinary tract infection.
- Patient who with serious morbid obesity, Pregnant women.
- Patient who had uncontrolled coagulopathy, uncontrolled hypertension, and uncontrolled Diabetes mellitus.

Tools of data collection:

The following tools (two tools) were utilized to collect data related to this study.

Tool I: Structure interview questionnaire:

This tool was developed and conducted by the researcher. It was included the following three parts:

Part (1): Socio demographic characteristics structured questionnaire: It was included demographic data of patients as: Age, gender, marital status, education level, occupation, occupation effort, residence, coexistence, monthly income, and BMI.

Part (2): Medical and surgical history data:

It was designed by the researcher to assess medical and surgical history including: Past medical and surgical data such as (presence of comorbidities, previous kidney related surgeries, type, site and laterality of surgery). Also present medical health history such as (Smoking, symptoms during urination, current site of stones, laterality of current kidney stones, current location of kidney stones, laterality of current ureter stones, current location of ureter stones, number of current stones, size of current stones type of current stones and application of DJ stent).

Part (3): Knowledge assessment questionnaire:

It was adapted by the researcher from **Abdelmowla et al. (2018); Elsayed, (2019); Abdelwahab et al. (2021)** concerned with assessment of patients' knowledge

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regarding ESWL & instructions to be followed prior, during and after lithotripsy, as well as DJ stent care & preventive measures to prevent the recurrence of urinary tract stones.

Scoring system for patients' knowledge questions: The correct answers were given one score (1) and the wrong answers were given zero score (0). These scores were summed-up and converted into a percent score.

Total knowledge score: 27 equal (100%)

The total score was calculated as follows:

- Good knowledge level at $\geq 75\%$ (equal ≥ 21) score.
- Average knowledge level at $50\% - < 75\%$ (equal $14 - < 21$) score.
- Poor knowledge level $< 50\%$. (equal < 14) score.

Tool II: Extracorporeal Shock Wave Lithotripsy Health Outcomes Assessment

Tool (ESWL-HOA): This tool included the following three parts:

Part (1): Modified Numeric Pain Rating Scale (NRS-11): Numerical Pain Rating Scale (NPRS) is a subjective measure (self-reporting) in which individuals rate their pain on an eleven-point numerical scale. The scale is composed of 0 (no pain at all) to 10 (worst imaginable pain). It was adopted from **Williamson and Hoggart (2005)** to assess pain severity with the following rating system:

Scoring system for pain severity

- (0) Referred to no pain.
- (1-3) Referred to mild pain.
- (4-6) Referred to moderate pain.
- (7-9) Referred to severe pain.
- (10) Referred to worst pain.

Part (2): Standardized Grading of Shock Wave Lithotripsy Complications with Modified Clavien System scale. It was adopted from **Mittal et al. (2016)** to grade post-procedural complications of ESWL in relation to various stone and shock wave parameters, through assessing incidence of each of described

problems which the patient may had one complication or more related to each grade.

Scoring system of complication

Complications were graded according to severity into **4 grades** (0, I, II, \geq III) which in each grade, it was determined according to incidence of either of the sub scaled complications in term of **yes (1)/ No (0)**.

Total score was divided into:

- Score (0) Grade: indicated no complication
- Score I-II Grade: indicated minor complication
- Score \geq III-Grade: indicated major complication

Part (3): Rand short form 36 items questionnaire: It was adopted from **Ware and Sherbourne (1992)** to assess patients as regards quality of life (HRQoL) after surgical intervention with shock wave lithotripsy (SWL) and to evaluate the factors affecting HRQoL in urolithiasis patients according

eight health concepts. It contains 36 questions and measures quality of life. It is divided into eight scales: Physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/ fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health plus one health comparison question (health change).

Scoring system for the RAND 36-Item Health Survey is a **two-step** process. **First**, preceded numeric values. Note that all items are scored so that a high score defines a more favorable health state. In addition, each item is scored on a 0 to 100 range so that the lowest and highest possible scores are 0 and 100, respectively. Scores represent the percentage of total possible score achieved. **In step 2**, items

in the same scale are averaged together to create the 8 scale scores

Tools validity and reliability

Content validity: The tools were reviewed by a panel of five experts from Medical Surgical Nursing field at Faculty of Nursing Benha University to test the relevance, clarity of tools' content, comprehension, understanding, applicability, and necessary modification was done accordingly.

Reliability was testing statistically to assure that the tools are reliable before data collection. Testing reliability of the developed tools was done through Alpha Cronbach test (**0.86**) for patients' knowledge assessment questionnaire, pain score, incidence of complication & QOL.

Pilot study

After the tools have been designed, they were tested through a pilot study, which was done before embarking on the field of work to check the clarity and feasibility of designed tools and to estimate the time needed to complete its items. it was carried out on 10% (9) of the sample to examine the clarity of questions and time needed to complete the study tools. Based on the results, patients included in the pilot study were included from the study subjects.

Ethical considerations:

The research approval was obtained from the ethical committee of Faculty of Nursing Benha University before initiating the study work. The researcher clarified the purpose and aim of the study to patients included in the study before data collection. The written consent was obtained from patients to participate in the study.

The researcher assured maintaining, anonymity and confidentiality of subjects' data and that, it will be used for research purpose only.

Field work:

- Once the researcher was interviewed with the patients to obtain consent and explain the purpose of the study, the data was collected pre and post ESWL procedure.
- Sampling was being extended over 8 months and starting at May 2021 till the beginning of January 2022, the researcher visited the Urology department (three days weekly (Saturday, Monday, and Tuesday) morning shift.
- The study was conducted according to four phases:

Phase I: Assessment phase:

During assessment phase the researcher was prepared and translated tools for data collection, as well as assessed patients in both intervention and control groups.

- The researcher took telephone number at the first contact to determine the next appointment in order to complete data collection process.
- It was filled by the patients in a time ranged from **35 to 40** minutes distributed as the following: Patients' socio-demographic characteristics (**tool I, part 1**) took about 5 minutes, patients' medical and surgical health (**tool I, part 2**) took about 5 minutes, and patient's knowledge (**pretest**) using (**tool I, part 3**) took about 10 minutes first time at outpatient clinics and urology department where patients scheduled and had an appointment before the procedure about 7 days) was one day before and day of procedure.
- As well as assess patient pain score, incidence of complication and quality of life before implementation the guidelines measured at first time (**After undergoing ESWL**) using (tool II) took about 15-20 minutes within 7 days to 14 days before

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guidelines implementations and after undergoing ESWL), which help in modifying guidelines.

Phase II: Planning Phase (Evidenced based guidelines regarding ESWL).

- Proposed guidelines general and specific objectives were designed based on predetermined subjects' need, relevant recent literature, and opinions of the nursing experts. This guideline was revised and modified based on the experts' comments, to be implemented using various methods including a booklet contained major headlines of Evidenced based guidelines regarding ESWL and strategies to prevent risks of stone recurrence, which was designed by researcher, and written in a very simple Arabic language, as well as supplemented by photos.

Phase III: Implementation phase:

- Implementation of guidelines lasted over a period of 8 weeks for all patient in the intervention group.
- Each patient was met in the morning shift. It was given to the patients individually; incorporating one family member was present for patient support, while control group was given routine care.
- Each session had taken about 35-45 minutes /day except for the session of discharge instructions, which took sixty minutes for three days per week. These sessions were conducted for small group ranged from 1-3 patients.
- The guidelines involved 3 scheduled sessions
- Each session was started by a summary about what has been discussed in the previous session and the objectives of the new session, also, the session ended by a summary of its contents and feedback. Suitable teaching media were used, included Pictures, handouts, videos and

booklet that was distributed to all patients that able to read and write. Also, the researcher communicated with patients via telephone call for instruction and reinforcement.

- The content of guidelines sessions covered in a booklet; each patient obtained a copy of the Arabic booklet.
- At last sessions, the researcher informed them that they will be evaluated by the researcher immediately.

Phase IV: Evaluation phase:

Evaluate the effect of implementing evidence-based guidelines among patients undergoing extracorporeal shock waves lithotripsy for urolithiasis and was evaluated by the researcher. This effectiveness was based on finding of differences or no differences between intervention and control groups Tools was used 3 times (immediate post, after one month & 3 months) of guidelines implementation which was conducted after discharge during follow up period at outpatient clinics or by telephone as the follow (Mittal et al., 2016):

- **Immediately** after the implementation the guideline, it was concerned with patients' knowledge using (tool 1, part 3), pain score, incidence of complication (Health Outcomes) using (tool II, part 1 and part 2).
- **One month** after the implementation the guideline, it was concerned with patients' knowledge using (tool 1, part 3) and (Health outcomes) using (tool II)
- **After 3 months** after the implementation the guideline, it was concerned with patients' knowledge using (tool 1, part 3) and (Health outcomes) using (tool II).

Statistical analysis:

Data entry and statistical analysis were done using the Statistical Package for Social Science (SPSS version 22.0). Descriptive statistics included frequencies and percentages, means and standard deviations. Inferential statistics as (Chi-square test) and Pearson correlation coefficient were used.

Results

Table (1): Shows that, there were no significant statistical differences between both groups in relation to all socio- demographic characteristics. As regards Age, results revealed that (42.5%) and (40.0%) of the intervention and control groups were aged between 30<40 years old with mean age (40.10±8.90 and 41.20±9.27, respectively). Concerning gender, it was founded that the intervention and control groups were males among (65.0% and 67.5%, respectively). In addition, had a secondary education among (40.0% and 37.5%, respectively).

Table (2): Shows that, there were no significant statistical differences between both groups according to present medical health history. As regards current site of stones, it was observed that (77.5% & 67.5%, respectively) among both intervention and control groups had kidney stones predominantly than ureter or bladder stones, with a severe pain which was reported a highest parentage as a symptom during urination among intervention and control groups with a percent of (72.5% & 60.0%, respectively). Concerning laterality of Current kidney stones, the highest percentages had right kidney stones among (47.5% & 40.0%, respectively) specialty in middle and renal pelvis stones among (40% & 32.5%, respectively) of both intervention and control group.

Figure (1): Shows that, there was no significant statistical difference between intervention and control groups regarding

their knowledge level during (**pre**) guidelines implementation at **P** value= (0.896). where (60.0% & 62.5%, respectively) of both groups had poor knowledge level. However, there was highly significant statistical difference regarding knowledge level for both intervention and control groups during post guidelines implementation at 3 months at (p-value =0.001**).

Table (3): Reveals that, there were significant statistical differences between both intervention and control groups during post guidelines implementation (Immediately, after one month and 3 months period) at (p-value = 0.008, <0.001** & <0.001**, respectively) in term of pain improvement to be finally (1.28±1.6 & 4.10±2.2) after three months.

Table (4): Reveals that, there were no significant statistical differences for both intervention and control groups regarding their grade of complication during (**pre and immediately post**) guidelines implementation indicating incidence of minor complication among (87.5% & 82.5%, respectively) at P -value =0.403. While there were highly significant statistical differences for both intervention and control groups during post guidelines implementation (one months & 3 months indicating non incidence of complication among (70.0%) of intervention group and (7.5%) of control group at P – value = <0.001**.

Table (5): Clarifies that, there were highly significant statistical differences between both groups during post guidelines implementation periods in term of improved QoL (8) domains with a mean score of (2135.4±338.9 & 1209.39±244.1, respectively) during one month period & (3074.0±427.3 & 1355.6±281.8, respectively) during 3 months periods post guidelines implementation at P- value = <0.001**.

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Table (6): Shows that, there was significant negative correlation between total knowledge and pain, incidence of complication, while a positive correlation with QOL in intervention group at $p=0.015^*$, 0.010^* & 0.009^* , respectively) post 3 months guidelines implementation, also there was highly significant negative correlation between incidence of complications with pain and QOL ($p\text{-value} = <0.001^{**}$) in intervention group post 3 months of guidelines implementation .While there was highly significant negative correlation between incidence of complications and QOL ($p\text{-value} = <0.001^{**}$) in control group post 3 months of guidelines implementation.

Table (1): Distribution of studied patients regarding to their socio-demographic characteristics, intervention, and control groups (n= 80).

Items	Patient data	Intervention group n=40		Control group n=40		X ²	P- value
		N	%	N	%		
Age (in years)	20 -<30	6	15.0	5	12.5	0.521	0.914
	30 -<40	17	42.5	16	40.0		
	40 -<50	13	32.5	13	32.5		
	50-60	4	10.0	6	15.0		
	Mean ±SD	40.10±8.90		41.20±9.27		t=0.398	0.541
Sex	Male	26	65.0	27	67.5	0.56	0.813
	Female	14	35.0	13	32.5		
Marital status	Single	7	17.5	5	12.5	3.150	0.369
	Married	29	72.5	30	75.0		
	Divorced	3	7.5	1	2.5		
	Widow	1	2.5	4	10.0		
Educational level	Illiterate	5	12.5	6	15.0	1.632	0.652
	Read and write	8	20.0	8	20.0		
	Secondary	16	40.0	15	37.5		
	University	11	27.5	11	27.5		
Occupation	Working	29	72.5	24	60.0	2.234	0.327
	Not working	11	27.5	16	40.0		
Occupational effort	Mild effort	13	32.5	16	40.0	0.857	0.651
	Moderate	19	47.5	17	42.5		
	Hard effort	8	20.0	7	17.5		
Residence	Rural	29	72.5	23	57.5	1.978	0.160
	Urban	11	27.5	17	42.5		
Coexistence	Alone	5	12.5	0	0.0	6.216	0.145
	With family	35	87.5	39	97.5		
	Others	0	0.0	1	2.5		
Monthly income (As patient reported)	Sufficient	25	62.5	27	67.5	0.220	0.639
	Insufficient	15	37.5	13	32.5		
Body Mass Index (BMI)	Underweight< 18.5)	4	10.0	2	5.0	1.024	0.599
	Normal (18.5-24.9)	26	65.0	24	60.0		
	Overweight (25- 29.9)	8	20.0	12	30.0		
	Obese≥ 30	2	5.0	2	5.0		
	Mean ±SD	24.10 ± 2.79		24.20 ± 2.80		t=0.152	0.879

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Table (2): Distribution of studied groups according to their present medical health history, intervention, and control groups (n= 80).

Items	Present medical data	Intervention group 40		Control group 40		X ²	P-value
		N	%	N	%		
Smoking	Yes	14	35.0	15	37.5	0.007	0.934
	No	26	65.0	25	62.5		
Symptoms during urination	Sever pain	29	72.5	24	60.0	8.699	0.069
	Difficulty & burning	13	32.5	19	47.5		
	Urinary Retention	3	7.5	2	5.0		
	Oliguria	9	22.5	6	15.0		
Current site of stones	Kidney stones	31	77.5	27	67.5	1.003	0.317
	Ureter stones	9	22.5	13	32.5		
	Bladder stones	0	0.0	0	0.0		
Laterality of Current kidney stones	Right	19	47.5	16	40.0	1.710	0.635
	Left	12	30.0	11	27.5		
Current location of kidney stones	Upper	5	12.5	4	10.0	2.614	0.455
	Middle and renal pelvis	16	40.0	13	32.5		
	Lower	10	25.0	10	25.0		
Laterality of Current ureter stones	Right ureter	6	15.0	9	22.5	3.752	0.290
	Left ureter	3	7.5	4	10.0		
Current location of ureter stones	Proximal ureter	8	20.0	7	17.5	4.628	0.201
	Middle ureter	1	2.5	5	12.5		
	Distal ureter	0	0.0	1	2.5		
Number of current stones	1	36	90.0	35	87.5	1.514	0.469
	≥2	4	10.0	5	12.5		
Size of current stones	Less than 5 mm	6	15.0	0	0.0	9.483	0.324
	5mm- < 1cm	24	60.0	23	57.5		
	1-2 cm	9	22.5	17	42.5		
	More than 2cm	1	2.5	0	0.0		
	Mean ±SD	8.15±4.27	9.75±4.10	t=1.709	0.091		
Types of current stones	Ca Oxalate	29	72.5	26	65.0	2.626	0.453
	Struvite	1	2.5	1	2.5		
	Uric acid	8	20.0	10	25.0		
	Cysteine	2	5.0	3	7.5		
Application of DJ stent	1 stent	10	25.0	15	37.5	0.853	0.356
	2 stents	3	7.5	2	5.0		
	More than 2 stent	0	0.0	0	0.0		
	None	27	67.5	23	57.5		

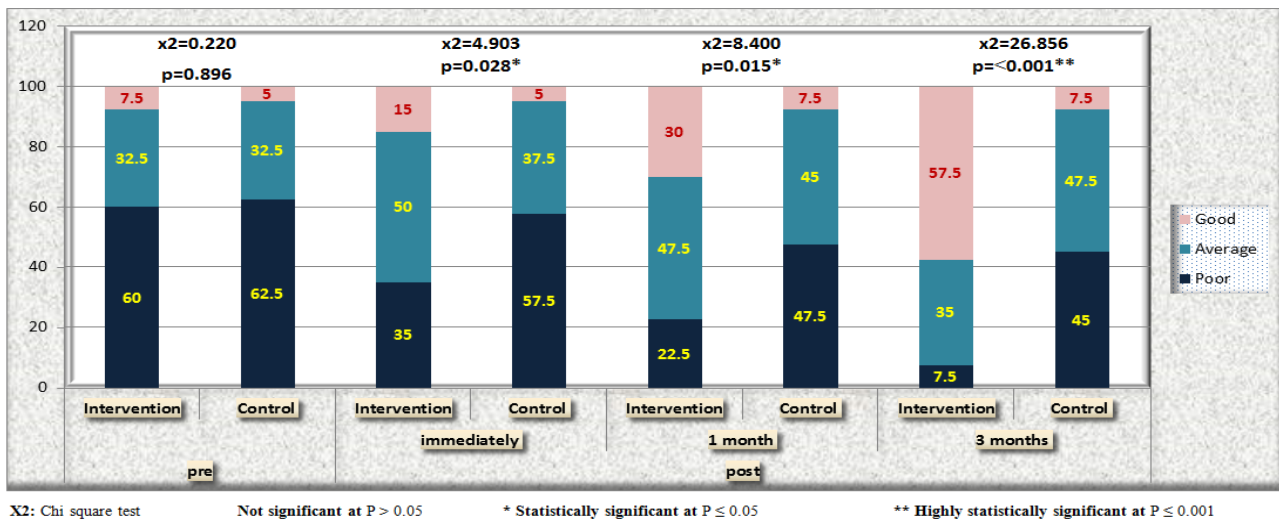


Figure (1): Comparison between studied groups regarding to their levels of total knowledge during different study periods (pre, Immediately, one months & 3 months post guidelines implementation), intervention and control groups (n=80).

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Table (3): Comparison between studied groups regarding to their pain score during different study periods (pre, Immediately, one month & 3 months post guidelines implementation), intervention and control groups (n= 80).

pain score	Pre (After ESWL)				X ² & P-value	Post														
	intervention group (n=40)		Control group (n=40)			immediately				one month				3 months						
	N.	%	N.	%		N.	%	N.	%	N.	%	N.	%	N.	%	N.	%	X ² & P-value		
																			N.	%
None	2	5.0	4	10.0	2	5.0	4	10.0	9.169& 0.041*	9	22.5	4	10.0	13.710& 0.003*	24	60.0	6	15.0	25.554& <0.001**	
Mild	3	7.5	5	12.5	7	17.5	6	15.0		14	35.0	5	12.5		13	32.5	12	30.0		
Moderate	12	30.0	7	17.5	19	47.5	7	17.5		17	42.5	25	62.5		3	7.5	18	45.0		
Severe	20	50.0	22	55.0	11	27.5	22	55.0		0	0.0	6	15.0		0	0.0	4	10.0		
Worst	3	7.5	2	5.0	1	2.7	1	2.5		0	0.0	0	0.0		0	0.0	0	0.0		
Mean +SD •	6.48+1.67		6.35+2.6		t= 0.251 & 0.803	4.95+1.3		6.13+2.3		t= 2.743& 0.008*	2.83+1.5		4.90+2.0		t= 5.050& <0.001**	1.28+1.6		4.10+2.2		t= 6.490& <0.001**

**** A highly statistical significant difference P ≤ 0. 001)**

Table (4): Comparison between studied groups regarding to their grade of complication during different study periods (pre, Immediately, one months & 3 months post guidelines implementation), intervention and control groups (n= 80).

Grade of complication		Pre (After ESWL)					Post														
		intervention group (n=40)		Control group (n=40)		χ ² & P- value	Immediately				One month				3 months						
							intervention group (n=40)		Control group (n=40)		χ ² & P- value	intervention group (n=40)		Control group (n=40)		χ ² & P- value	intervention group (n=40)		Control group (n=40)		χ ² & P- value
		N	%	N	%	N	%	N	%	N		%	N	%	N		%				
None	Grade 0	0	0.0	0	0.0	1.818	0	0.0	0	0.0	1.818&	10	25.0	0	0.0	15.833&	28	70.0	3	7.5	37.618&
Mino r	Grade I	25	62.5	19	47.5	0.403	25	62.5	19	47.5	0.403	25	62.5	25	62.5	<0.001**	12	30.0	23	57.5	<0.001* *
	Grade II	10	25.0	14	35.0		10	25.0	14	35.0		4	10.0	8	20.0		0	0.0	8	20.0	
	Total	35	87.5	33	82.5		35	87.5	33	82.5		29	72.5	33	82.5		12	30.0	31	77.5	
Majo r	Grade III	5	12.5	7	17.5		5	12.5	7	17.5		1	2.5	7	17.5		0	0.0	6	15.0	
	Grade IV	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0					
	Grade V	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0					
	Total	5	12.5	7	17.5	5	12.5	7	17.5	1	2.5	7	17.5	0	0.0	6	15.0				

** A highly statistical significant difference P ≤ 0. 001)

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Table (5): Comparison between studied groups regarding to their health-related quality of life domains during different study periods (pre, one months & 3 months post guidelines implementation), intervention and control groups (n= 80).

Domains	Pre (After ESWL)					Post									
	Intervention group n=40		Control group n=40		t test P- value	one month				3 months					
	\bar{x}	\pm SD	\bar{x}	\pm SD		Intervention group n=40	Control group n=40	t test P-value	Intervention group n=40		Control group n=40			t test P-value	
					\bar{x}				\pm SD	\bar{x}	\pm SD	\bar{x}	\pm SD		\bar{x}
Physical functioning	274.94	60.3	309.50	77.4	1.455 0.650	669.38	132.0	372.53	70.9	6.486 <0.001**	944.39	129.0	397.85	80.1	12.772 <0.001**
Role limitation due to Physical health	148.6	32.0	152.5	32.2	1.758 0.938	228.0	29.5	161.75	30.6	8.276 0.001**	304.25	45.9	174.75	32.1	10.791 <0.001**
Role limitation due to emotional problems	127.86	21.0	128.25	18.6	0.758 0.938	171.25	24.0	139.25	20.3	4.381 0.007*	271.0	36.4	158.25	23.0	11.581 <0.001**
Energy /fatigue	108.89	19.5	112.3	21.3	0.864 0.245	193.75	25.7	130.5	23.0	9.374 <0.001**	282.29	40.0	141.48	28.6	9.435 <0.001**
Emotional wellbeing	128.50	31.8	129.75	32.1	1.958 0.988	237	48.7	151.85	35.1	8.475 <0.001**	425	51.3	173	40.2	29.894 <0.001**
Social functioning	35.63	8.3	38.13	11.2	1.861 0.066	118.1	26.1	48.13	10.5	8.890 0.001**	177.50	25.4	62.63	15.1	21.971 <0.001**
Pain	48.13	15.5	52.0	14.9	0.978 0.316	121.0	17.9	65.75	15.2	6.147 <0.001**	176.13	24.8	76.88	16.6	13.29 <0.001**
General health	109.42	29.3	100.39	30.9	0.943 0.998	397.0	64.5	139.63	38.5	16.016 <0.001**	493.51	74.5	170.76	46.1	19.37 <0.001**
Total	981.97	217.7	1022.8	238.6	0.994 0.898	2135.4	338.9	1209.39	244.1	11.696 <0.001**	3074.0	427.3	1355.6	281.8	29.467 <0.001**

** A highly statistical significant difference $P \leq 0.001$)

Table (6): Correlation between total knowledge and incidence of complications with pain and HRQoL of the studied patients after 3 months of guidelines implementation, intervention, and control groups (n= 80).

Variable	Total knowledge post 3 months				Incidence of complications post 3 months			
	intervention		Control		Intervention		Control	
	r	P- value	r	P- value	r	P- value	r	P- value
Pain	-0.400	0.015*	-0.196	0.225	-	-	-	-
Incidence of complications	-0.759	0.010*	-0.159	0.245	-	-	-	-
HRQoL	0.530	0.009*	0.042	0.779	-0.234	<0.001**	-0.581	<0.001**

**** A highly statistical significant difference $P \leq 0.001$)**

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Discussion

Regarding to socio demographic characteristics of both groups, there were no significant statistical differences between both groups in relation to all socio- demographic characteristics which reflect homogeneity of both groups. As regard to Age, the present study revealed that about two fifths of the intervention and control groups were aged between thirty less than forty years old with mean age (40.10±8.90 and 41.20±9.27). From the researcher point of view, this may refer to age is considered a risk factor of renal stone formation. where the earlier onset of the first episode, the more likely a person will be multiple stone former.

These findings were supported by findings of **Demir et al. (2021)** who conducted a study about “Usability of shear wave elastography to predict the success of extracorporeal shock-wave lithotripsy” they reported that the mean age of the patients was thirty-seven. While coming into contradiction with **Li et al. (2022)** who conducted a study about “Should we treat asymptomatic concurrent contralateral renal stones; a longitudinal analysis” and stated that majority of patients were fifty-nine years old.

Concerning gender of the studied subjects, the present study findings revealed that about two thirds of the intervention and control groups were males. This finding was to some extent in agreement with **Sholihin et al., (2019)** who conducted a study about “ESWL Effectiveness for Lower Pole Kidney Stones” They stated that over-whelming majority of the studied subjects were males. The findings could be explained by that anatomical difference between males and females; this may cause accumulation and stagnation of urine in the bladder for longer times.

On the other hand, this finding was in contrast with the result of a study done by **Narain and Hedayatullah (2021)** which entitled “Clinico-demographic and dietary profile of patients diagnosed with kidney stones: prospective study” and stated that females were representing more than half of studied sample.

Regarding patient level of education, the current study revealed that around two fifths among intervention and control group had secondary education. This could be explained as the some of the subjects were from rural areas and it depends on the site/region from which the study sample were drawn.

This finding was in agreement with **Ismael (2021)** who carried out a study about “Patient's Awareness Regarding Prevention of Recurrent Urinary Tract Stones in Surgical Teaching Hospital in Sulaimani City, Iraq.” and demonstrated that almost half of the patients had primary and secondary education level, on contrary **Alghamdi et al. (2018)** conducted a study about “ Awareness about Symptoms and Role of Diet in Renal Stones among General Population of Albaha City” and stated that the most of respondents had high education.

As regards current site of stones, current study revealed that more than three quarter of intervention group and two third of control group had kidney stones predominantly than ureter stones and bladder stones respectively. These finding could be explained that kidney stones are most common among middle-aged adults and more than two fifth of studied subjects was aged between thirty-one to forty years old. This was highly supported by the results of **Saeed et al., (2020)** who studied “The Prevalence of Incidentally Detected Urolithiasis in Subjects Undergoing

Computerized Tomography” and stated that most of the stones were found in the kidneys whereas no stone was detected in the urinary bladder.

Conversely, this finding was disagreed with **Yongzhi et al., (2018)** who studied “Risk factors for urinary tract infection in patients with urolithiasis primary report of a single center cohort” and revealed that ureteral calculi were the most common type of condition.

Regarding stone location, the current study revealed that middle and renal pelvis stones represented highest percentage among two fifth of intervention group and about two third of control group. As well as around one fifth of studied sample had right ureter stones and located in proximal site. This finding could be explained by those stones may get stuck as they exit the renal pelvis or take longer to move through the ureter, causing severe pain and other symptoms. This finding was highly supported by **Elsayed (2019)** who conducted a study about “Impact of Nursing Protocol on Stone Clearance Rate and Acute Complications Following Extracorporeal Shock Wave Lithotripsy” and reported that two fifths of control group diagnosed with stone at middle calyx of the kidney and about half among intervention group diagnosed with stone at the same site.

On the other hand, this finding was in contrast with a study done by **Elmasry et al. (2020)** who pointed out in their study about “Success factors of extracorporeal shock wave lithotripsy for renal and upper ureteric calculi in adults” and reported that about half of all studied patients had upper (proximal) ureter stones.

As regards number and size of stone, the current study revealed that most of both groups had single stone and about three fifths of intervention and control group had a stone sized between 5mm- < 1cm with a mean of stone size (**8.15±4.27** mm and **9.75±4.10** mm, respectively). The possible explanations for this

range of the size could be that calculus less than 5mm could be passed spontaneously and asymptotically, while a larger calculus might obstruct the ureter and block the flow of urine.

These findings were matched with **Shinde et al. (2018)** who carried out in their study about “Factors Affecting the Outcome of Extracorporeal Shockwave Lithotripsy in Urinary Stone Treatment” that about three quarters of the studied patients had a stone sized < 10mm with mean of stone size was 9.0 ± 2.5 mm.

On the other hand, this finding was incongruity with **Al-Zub et al. (2021)** who conducted in their study about “The effect of stone and patient characteristics in predicting extracorporeal shock wave lithotripsy success rate: A cross sectional study” that more than two thirds of studied group had less than 5mm.

Regarding patient knowledge post guidelines implementation, the current study revealed that there was highly significant statistical difference regarding to knowledge level between both intervention and control groups during post guidelines implementation at 3 months at (p- value =0.001**). Where, total knowledge of intervention group was gradually improved during post guidelines implementation to reach a good knowledge level among less than three fifths, while around less than half of control group had average knowledge level after 3 months. These may be explained due to effect of evidence-based guidelines sessions.

This finding was agreement with **Mohamed et al., 2015** who found that there was highly statistically significant difference between knowledge of the intervention group who had a significant increase the knowledge level with P value was (0.001*) post program and in follow up after 3 months compared with control group and preprogram.

Concerning pain severity pre guidelines implementation, the current study

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revealed that there was no significant statistical difference between both intervention and control groups during (**pre**) guidelines implementation at P- value = (0.803) with mean pain score of (6.48±1.67&6.35±2.6, respectively). Pain was manifested in a variant degree at first assessment during pre-guidelines implementation among both intervention and control groups which about half of intervention group had experienced worst pain, and more than half of control group had experienced severe pain. This finding could be explained that pain is the most common side effect related to local ESWL site and fragmented stone movement.

This finding was congruent with **Boveland et al. (2018)** who conducted in their study about “The Influence of Pain on the Outcome of Extracorporeal Shockwave Lithotripsy” that about half of the patients had moderate pain and one third of the patients had severe pain.

Concerning pain severity Post guidelines implementation, the current study revealed that there were statistically significant differences between intervention and control groups during post guidelines implementation (Immediately, after one month and 3 months period) at (p- value = 0.008, <0.001**&<0.001**, respectively) in term of pain improvement to be finally (1.28±1.6&4.10±2.2) after three months. This finding could be explained that the effectiveness of evidence base nursing guidelines for pain management post ESWL.

These finding was in agreement with **Elsayed (2019)** who reported that the differences were highly statistically significant within both groups and between the two groups in the three follow up period (p=0.000) (p=0.000) (p=0.000) respectively of nursing protocol. where pain severity was improver between intervention group

than control group which about two thirds of intervention group had no pain, while more than one fourth of control group had no pain.

Concerning minor and major ESWL complications, the current study illustrated that, there were no significant statistical differences for both intervention and control groups regarding their grade of complication during (**pre and immediately post**) guidelines implementation which majority incidence of complications were minor at (P -value =0.403). While there were highly significant statistical differences for both intervention and control groups during post guidelines implementation (one months & three months) indicating non incidence of complication among more than two thirds of intervention group at P – value = <0.001**. This finding could be explained that the effectiveness of evidence base nursing guidelines for pain management post ESWL.

These findings were highly supported with **Tzelves et al. (2021)** who reported that in total, about one fifth of patients suffered from Clavien I–II (minor) and minority of them from Clavien III–IV (major) complications.

Concerning patient quality of life pre guidelines implementation, the current study showed that there were no significant statistical differences in HRQoL between intervention & control groups during (**pre**) guidelines implementation with a mean score of (981.97±217.7& 1022.8±238.6, respectively) at (P-value = 0.898), which around three quarters of the intervention and control groups had poor quality of life level pre guidelines implementation. These findings may be explained that preoperative SF 36 questionnaire which researcher had been done for patients with urolithiasis undergoing ESWL had lower score of the quality of life

in almost all dimensions or domains of health.

This finding was supported with **Gvozdić et al. (2020)** who studied “The examination of the quality-of-life changes of patients with urolithiasis regarding different methods of treatment” and stated that quality of life score was statistically significantly lower in comparison to the patients of the ESWL group. The low scores were also noted in the following health dimensions: bodily pain, overall health, vitality, emotional role, and mental health.

On the other hand, **Guler et al. (2021)** who studied “Factors affecting success in the treatment of proximal ureteral stones larger than 1 cm with extracorporeal shockwave lithotripsy in adult patients” and reported that lithotripsy patients reported only lower bodily pain subscale scores, which may reflect their experience with pain due to stone formation.

Concerning patient quality of life post guidelines implementation, the current study showed that there were highly significant statistical differences between both groups during post guidelines implementation periods in term of improved HRQoL with a mean score of (2135.4±338.9& 1209.39±244.1, respectively) during one month period & (3074.0±427.3&1355.6±281.8, respectively) during 3 months periods post guidelines implementation at P- value = <0.001**. This could be explained by higher stone free rate, the effect of evidence-based guidelines and patients education including home care and discharge instructions (teaching booklet). As well as the treatment of renal stone improves all domains of quality of life.

These findings were in the same line with **Abdelmowla et al. (2017)** who showed that there is a statistically significant difference

regarding the quality of life of patients postoperatively between two groups of patients in several domains of health. With the higher score on SF 36 questionnaire, all domains of quality of life improve in intervention group patients. Also, **Sahin et al. (2015)** whose study was entitled “Stone size and quality of life: A critical evaluation after extracorporeal shock wave lithotripsy” and stated that evaluation of the QoL scores in three groups showed that cases with larger stone still had lower QoL scores during three months evaluation among ESWL group.

Pertaining to correlation between total knowledge and incidence of complications with pain and HRQoL of the studied patients, the current study revealed that there was significant negative correlation between total knowledge with pain and incidence of complications, while a positive correlation with HRQoL in intervention group at p= 0.015*, 0.010*& 0.009*, respectively). These finding could be explained that acquired knowledge from evidence-based guidelines play a vital role in improving patients’ health outcomes.

These findings were in the same line with **Abdelmowla et al. (2017)** who reported that improving patients’ level of knowledge had a significant effect on reducing or preventing postoperative complications. Also, **Abdelwahab et al. (2020)** who revealed that both knowledge and QoL score of the study group correlated significantly and positively.

Regarding correlation between incidence of complications with HRQoL, the current study revealed that there was highly significant negative correlation between incidence of complications with HRQoL at (p-value = <0.001**) in both intervention and control groups post three months of guidelines

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implementation. This may be due to that impairment in health-related quality of life associated with incidence of complications which increase risk of post operative complications worsens patients' quality of life.

This study was matched with that of **Archer et al. (2019)** who conducted a study about "Surgery, Complications, and Quality of Life: A Longitudinal Cohort Study" and stated that there was significant negative correlation with QoL, patients who experience major surgical complications report significantly reduced levels of physical and mental QoL ($P < 0.05$).

Conclusion

Implementation of evidence-based guidelines was effective in improving knowledge about ESWL, preparation post ESWL & DJ stent care, in term of significantly higher level among intervention group than control group, as well as significantly improved health outcomes among intervention group than control group with lower pain score, incidence of complications, and a positive impact on patients' HRQoL.

Recommendations

- Evidence Based Guidelines should be provided with the cooperation between urology nurse specialists and specialized urology team department till patients' discharge.
- Encourage follow up visits for urological outpatient clinics, home visits or telephone follows up to evaluate renal stone patients' progress, improve clinical outcomes, QOL and prevent complications.
- Continuous evaluation of patients' knowledge regarding post ESWL instructions periodically to determine the effect of guidelines implementation during follow up periods.

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تأثير الإرشادات القائمة على الأدلة على النتائج الصحية بين المرضى الخاضعين لموجات الصدمات خارج الجسم لتفتيت الحصوات البولية

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يعد تطبيق الإرشادات القائمة على الأدلة أداة فعالة في تحسين مستوى المعلومات وكذلك النتائج الصحية لدى المرضى الخاضعين لتفتيت الحصوات البولية عن طريق موجات الصدمات خارج الجسم، حيث يعتبر تفتيت الحصوات باستخدام موجات الصدمات من أسلم الطرق وأبسطها وأقلها آثار جانبية ومضاعفات مقارنة بالطرق الأخرى عندما يتم إتباع الإرشادات المناسبة القائمة على أساس ودليل علمي. كذلك يعتبر تعديل نمط الحياة بالإضافة الي تفتيت الحصوات بموجات الصدمات الطريق الأمثل لعلاج حصوات الحالب والكلي الأصغر من ٢ سم. لذلك هدفت الدراسة الي تقييم تأثير الإرشادات القائمة على الأدلة على النتائج الصحية بين المرضى الخاضعين لموجات الصدمات خارج الجسم لتفتيت الحصوات البولية. وقد أجريت الدراسة في وحده تفتيت الحصوات بموجات الصدمات خارج الجسم بقسم المسالك البولية بمستشفى بنها الجامعي على ٨٠ مريضاً ومريضه. حيث كشفت النتائج على تحسن ملحوظ في مستوى المعلومات لدي المرضى بمجموعة التدخل عن المجموعة الضابطة، كذلك هناك إنخفاض ملحوظ ذو دلالة إحصائية بمعدل حدوث المضاعفات ودرجة الألم وكذلك تحسن جودة حياة المرضى بمجموعه التدخل عنه بالمجموعة الضابطة. كما أوصت الدراسة بضرورة تقديم الإرشادات القائمة على الأدلة بالتعاون بين اختصاصي تمريض المسالك البولية وأطباء المسالك البولية المتخصصين. كما أنه يفضل إجراء المزيد من الدراسات لتقييم تأثير الإرشادات القائمة على الأدلة مع المتابعة طويلة الأجل لتكرار ظهور الحصوات البولية بعد تفتيتها بموجات الصدمات خارج الجسم.