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Original Article

A Comparative Analysis of Surgery and Radiofrequency Therapy for Urinary Incontinence in Iranian Women: Health-Related Quality of Life Improvements and Short-Term Cost-Utility Analyses

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Abstract

Introduction: This study evaluated the health-related quality of life (HRQOL) outcomes and the short-term cost-utility of surgery versus radiofrequency (RF) in treating urinary incontinence (UI) among Iranian women.

Methods: This prospective non-randomized cohort study with economic evaluation assessed the cost-utility of surgery versus RF from the Iranian health system's perspective. HRQOL was measured using the EuroQol five-dimensional five-level (EQ-5D-5L) and PRAFAB Urinary Incontinence questionnaires, with data collected from 79 women with UI before and three months after the intervention. Costs were calculated based on hospital records. The final outcome was the quality-adjusted life years (QALYs), and the incremental cost-effectiveness ratio (ICER) was calculated.

Results: The study sample had an average age of 51.43 years. Surgical intervention led to a significant improvement in HRQOL, with a mean utility increase from 0.21 to 0.70 and a decrease in PRAFAB incontinence severity scores. RF treatment also improved HRQOL, with utility increasing from 0.50 to 0.86. Moreover, the mean cost of surgery was USD2,200, significantly higher than that of RF, which was USD 622.52. The ICER for surgery compared to RF was USD12,724.93, indicating that surgery is cost-effective.

Conclusion: Surgery and RF both improve HRQOL, with surgery offering a greater QALY gain at a higher cost. Overall, surgery is a cost-effective treatment option compared to RF, supporting its inclusion in treatment guidelines.

Keywords: Urinary incontinence, Surgery, Radiofrequency, Health-related quality of life, Cost-utility analysis

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1. Introduction

The development of systematic decision-making processes in health systems is crucial for achieving universal health coverage, which ensures that all individuals receive quality health services without financial hardship (1). In addition, efficient use of health resources is vital for the sustainability of health systems, especially given the limited resources available (2). Nonetheless, policymakers across countries with varying income levels face challenges in allocating resources to enhance the effectiveness and efficiency of new medical technologies (3). Economic evaluations provide the best evidence to guide decision-makers in choosing new treatment methods and technologies while considering their opportunity costs (2, 4).

Pelvic floor disorders are considered a serious health issue characterized by the descent of pelvic organs (e.g., the bladder, uterus, and rectum) from their normal anatomical positions, leading to complications like urinary incontinence (UI) and other sexual and functional disorders (5, 6). UI is the involuntary leakage of urine, which is often triggered by activities that increase intra-abdominal pressure, such as exercise, laughing, sneezing, or coughing (7). It can be classified as transient or chronic, with the latter often requiring long-term management (8). The prevalence of at least one pelvic floor disorder in women is approximately 23%, with rates increasing with age (8). In Iran, the overall prevalence of UI in women is estimated at 46%, indicating the urgent need for attention to this issue (9).

UI is not a natural consequence of aging but a pathological condition that impacts the quality of life (QOL) (10). Women with UI often experience depression, social

and sexual dysfunction, and increased dependency on caregivers. The initial management of UI includes lifestyle changes, behavioral therapies, weight reduction, and pelvic floor muscle exercises (10). However, some women require further interventions, such as pharmacotherapy, surgery, or the use of vaginal devices and new medical technologies (11). Surgical complications can include bleeding, urinary tract infections, and recurrence of UI, while less invasive alternatives, such as radiofrequency (RF) therapy, offer promising results (8, 12).

Moreover, surgical treatments for UI, including various techniques and procedures, come with potential risks, such as bleeding, infections, and recurrence of symptoms (6). Non-surgical options, including medications and energy-based treatments, offer alternative approaches. For instance, RF treatment, a non-surgical method, uses electromagnetic waves to stimulate tissue regeneration and strengthen pelvic floor muscles, thereby presenting a promising alternative to traditional surgical methods (6).

The economic burden of UI is substantial, with costs increasing globally. In the U.S., the national cost of UI was estimated at $82.6 billion in 2020, with direct medical costs accounting for a significant portion (12). Similar trends are observed in Europe, with increasing costs projected in the coming years. Accordingly, addressing these costs through efficient and effective treatment options is crucial for optimizing health care expenditures (13).

Given the increasing demand for effective UI treatments due to the aging population, economic evaluations are crucial (3). The introduction of new technologies and interventions, such as RF treatments, highlights the need for rigorous economic evaluations to determine their cost-effectiveness compared to traditional methods. Therefore, this study seeks to compare the improvement of health-related QOL (HRQOL) and evaluate the short-term cost-utility of surgical treatment versus RF therapy in UI management among Iranian women, with the goal of updating national treatment guidelines with more cost-effectiveness.

2. Methods

This prospective non-randomized cohort study with economic evaluation assessed the cost-utility of reconstructive surgical interventions compared to RF treatment for UI from the perspective of the health system in Iran. The analysis adhered to Iran's national protocol for treating UI and considered costs and outcomes from the health system's perspective.

The cost analysis included the expenses of performing the interventions, pre-intervention and post-intervention costs, and related incidental costs. Additionally, outcomes were measured before the intervention and three months after the intervention using data collected from patients in Tehran. Both cost and effectiveness aspects are detailed in this analysis.

2. 1. Outcome Assessment

The quality-adjusted life year (QALY) was the final outcome measure. HRQOL was assessed using the EuroQol five-dimensional five-level (EQ-5D-5L) questionnaire, administered once before treatment and again three months post-treatment. In addition, patients were coded based on their treatment type and their pre-treatment and post-treatment questionnaire responses. Responses were scored from 1 to 5 on the EQ-5D-5L scale, with health profiles ranging from the highest QOL (11111) to the lowest QOL (55555). The utility weight for each health state before and after the intervention was estimated using the value set for Iran (14).

To calculate QALYs, utility values are derived from the EQ-5D scores using the Iranian value set coefficients. Assuming that the treatment's effectiveness is maintained for one year, QALY values are calculated based on these utility values. The average QALY values before and after the intervention in both groups are then used for the final evaluation. QALY estimates were obtained by integrating these values over the 1-year horizon. Further, incremental QALY was calculated as the difference between the mean QALY in the surgery and RF groups.

Furthermore, the PRAFAB questionnaire was utilized to estimate the effectiveness of the interventions and compare the reported utility based on the effectiveness of the treatments. This questionnaire assesses the use of protection, the amount and frequency of UI, the impact on daily activities, and body mental image, with scores ranging from 1 to 4, resulting in a total score between 5 and 20. The Persian version of this questionnaire has been validated for simplicity, comprehensibility, and accuracy by urologists, gynecologists, and pelvic physiotherapists, making it a suitable tool for assessing UI in Iranian women. The PRAFAB questionnaire provided scores before and three months after the intervention to assess treatment effectiveness (15).

2. 1. 1. Correlation Test of Utility Changes and Incontinence Severity

Pearson correlation analysis was used to examine the correlation between changes in utility and incontinence severity. This test evaluates how changes in utility align with those in the clinical status of patients, indicating the extent to which utility changes are attributed to alterations in disease severity. This analysis was separately conducted for patients undergoing surgical interventions and those receiving RF treatment.

2. 1. 2. Data Collection Protocol and Tools

Data were collected in person through in-depth interviews, with the researcher completing the questionnaires. The data collection process involved two comprehensive, multi-part questionnaires administered before and three months after the interventions.

Demographic Data: The first section of the questionnaire gathered demographic information, such as age, marital status, education level, parity, type of delivery, occupation, insurance coverage, and comorbid conditions (e.g., diabetes and hypertension) that could affect HRQOL. It

also collected data on the history of the current disease and any prior medical or surgical treatments.

Urinary Incontinence Severity: The second section assessed the status and severity of UI using the PRAFAB questionnaire, which measured protection use, the amount and frequency of incontinence, its impact on daily activities, and body image, with scores ranging from 1 to 4.

Health-Related Quality of Life: The third section exclusively used the EQ-5D-5L questionnaire to measure HRQOL, assessing mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, each with five levels of severity. The responses generated a unique 5-digit code representing the patient's health status, providing a comprehensive view of the interventions' impact on their QOL.

Each interview lasted 15–30 minutes, depending on the patient's literacy level, language, and age.

2. 2. Cost Assessment

This study calculated the direct medical costs of each treatment method from the perspective of the Iran health system. These costs included diagnostics, medications, treatment, consultations, and incidental expenses.

Surgical Intervention: For the surgical intervention, data were collected from medical centers managed by Shahid Beheshti University of Medical Sciences and relevant patient records from Taleghani and Shohadaye-Tajrish Hospitals for the years 2022 and 2023. All financial records were reviewed and adjusted according to the consumer price index of 2023. In addition, outliers were managed using a trimmed mean approach, removing 30% of extreme data points. Costs associated with pre-surgical diagnostic tests and consumables not included in hospital billing were also calculated. These items and services were identified in consultation with clinical experts, and unit costs were determined based on the official public tariffs for 2023.

Radiofrequency Treatment: Due to the limited number of cases in public centers, private centers in Tehran, Urmia, and Mashhad were also surveyed for RF treatment. RF for UI treatment is a new technology in Iran, lacking specific tariff codes, which leads to variable pricing depending on the location and provider. Therefore, costs were estimated using the relative value codes for vaginal laser treatment, with adjustments made for various services and supplies before, during, and after the procedure, in consultation with clinical advisors.

The purchasing power parity value of USD/rial = 91,081 was utilized to convert the monetary values of cost variables in the analysis.

2. 3. Cost-Utility Analysis

To evaluate the short-term cost-utility analysis of the two treatment methods, both the average treatment costs and QALYs were calculated for each method. Using the following formula, the incremental cost-effectiveness ratio (ICER) was then computed to compare the two approaches:

$$ICER = C_1 - C_2/E_1 - E_2$$

In line with World Health Organization recommendations, the cost-effectiveness threshold for common disease interventions in Iran was set at one time the gross domestic product per capita. For this evaluation, the threshold was based on Iran's gross domestic product per capita for the year 2024, which is purchasing power parity USD 17,896 (1,630 million rials) (16).

3. Results

3. 1. Sample Population Characteristics of Outcome Estimates

This study assessed the severity of UI and HRQOL in a sample of 79 women with UI to evaluate the impact of surgery and RF on improving their condition. The average age of the participants was 51.43 years, with a standard deviation (SD) of 13.03 years. In addition, the majority of participants were homemakers (59%), while the least common occupation was retirement due to UI (34%). Furthermore, educational levels varied, with 22% of participants having no formal education or only elementary education, and another 22% having education beyond high school. Of the participants, 52% underwent surgical intervention, while 48% received RF treatment (Table 1).

3. 2. PRAFAB Urinary Incontinence Questionnaire Scores:

The results revealed that the mean incontinence severity scores decreased across all components after the surgical intervention. For example, the mean score of the first component (use of protective equipment) decreased from 1.95 before the intervention to 1.32 after the intervention. Moreover, the cumulative index of incontinence severity decreased from 14.54 to 8.02. Similar results were observed for the RF intervention. The mean score of the first component decreased from 1.95 before the intervention to 1.13 after the intervention, and the cumulative incontinence severity index decreased from 12.16 to 6.42 (Table 2).

3. 3. EuroQol five-dimensional five-level (EQ-5D-5L) Questionnaire Scores and Utility Weight Estimation:

The mean scores of the five dimensions of the EQ-5D questionnaire improved after the surgical intervention. For example, the mean score of the first dimension (mobility) decreased from 2.17 before the intervention to 1.41 after the intervention. Likewise, the average utility weight increased from 0.21 to 0.70 (Table 3).

Similar results were observed for the RF intervention. The mean score of the first dimension (mobility) decreased from 1.71 before the intervention to 1.26 after the intervention, while the average utility increased from

Table 1. Characteristics of the Sample Population for Severity of UI and Health-Related Quality of Life Assessment

Variable	Observations	Mean	Std. Dev.	Minimum	Maximum
Age	79	51.43	13.03	24	78
	Subgroup	Proportion (%)		Std. Err.	
Employment status	Homemaker	59		0.06	
	Employed	28		0.05	
	Retired	11		0.04	
	Retired due to urinary incontinence	1		0.01	
Education level	No formal education or only elementary education	34		0.05	
	Beyond high school	13		0.04	
	Diploma	32		0.05	
	Higher than diploma	22		0.05	
Intervention type	Surgery	52		0.06	
	Radiofrequency	48		0.06	

Note. UI: Urinary incontinence; Std. Dev.: Standard deviation.

Table 2. Mean Scores of the PRAFAB Questionnaire by Component and Cumulative Incontinence Severity Index Before and After Surgical and Radiofrequency Interventions

Component		Surgery		Radiofrequency	
		Mean	Std. Err.	Mean	Std. Err.
Use of protective equipment	Before intervention	1.95	0.17	1.95	0.20
	After intervention	1.32	0.13	1.13	0.09
Amount of urinary incontinence	Before intervention	3.05	0.18	2.71	0.19
	After intervention	1.71	0.16	1.21	0.10
Frequency of urinary incontinence	Before intervention	3.56	0.13	3.03	0.17
	After intervention	1.76	0.18	1.37	0.14
Impact of urinary incontinence on activities	Before intervention	2.56	0.15	1.79	0.17
	After intervention	1.56	0.13	1.24	0.09
Mental image of the body	Before intervention	3.41	0.13	2.68	0.16
	After intervention	1.68	0.15	1.47	0.12
Incontinence index	Before intervention	14.54	0.56	12.16	0.69
	After intervention	8.02	0.63	6.42	0.45

Note. PRAFAB Urinary Incontinence: ; Std. Err.: Standard error of the mean.

0.50 to 0.86 (Table 3).

3. 4. Correlation Test of Utility Changes and Incontinence Severity:

The results of the Pearson correlation test in the surgical intervention and RF intervention groups indicated a significant correlation between the utility values and the severity of incontinence index. The correlation coefficients in the surgery and RF groups were estimated at -0.692 ($P < 0.001$) and -0.772 ($P < 0.001$), respectively. Based on these findings, after the therapeutic intervention, as the severity of UI decreased, the patients' utility weights improved, and this relationship was statistically significant.

3. 5. Cost Estimation:

Surgery: Out of 204 records related to surgery from 2022 and 2023, 7 records were excluded due to incomplete billing components, leaving 187 records (78 from 2022 and 109 from 2023) included in the cost calculations for surgery. The average age of the patients at the time of hospitalization was 55.98 years (SD = 13.65). The mean, median, and trimmed mean costs of surgery are presented in Table 4. The trimmed mean (30%) cost of surgery in 2023 was estimated at USD 1432.6. Other costs related to surgery, including laboratory tests, diagnostic procedures, and consumables outside of the hospital bill before and after the surgical process, were estimated at USD 771.54.

Radiofrequency: The cost per stage of the RF intervention, including consumables, was calculated at USD 11.52, with a total of USD 345.84 for the required 3 treatment sessions. Other costs associated with the RF intervention were estimated USD 276.67.

3. 6. Short-Term Cost-Utility Analysis

The average cost of the RF method (USD 622.52) was

Table 3. Mean Scores of the EQ-5D Questionnaire by Dimension and Mean Utility Values Before and After Surgical and Radiofrequency Interventions

Variable		Surgery		Radiofrequency	
		Mean	Std. Err.	Mean	Std. Err.
EQ-D1 (mobility)	Before intervention	2.17	0.18	1.71	0.19
	After intervention	1.41	0.10	1.26	0.10
EQ-D2 (self-care)	Before intervention	1.32	0.11	1.16	0.10
	After intervention	1.10	0.07	1.03	0.03
EQ-D3 (usual activities)	Before intervention	2.90	0.15	2.05	0.19
	After intervention	1.44	0.11	1.21	0.07
EQ-D4 (pain/discomfort)	Before intervention	2.68	0.21	1.55	0.15
	After intervention	1.68	0.10	1.24	0.08
EQ-D5 (anxiety/depression)	Before intervention	3.78	0.20	3.55	0.21
	After intervention	2.27	0.18	1.55	0.14
Utility	Before intervention	0.21	0.05	0.50	0.05
	After intervention	0.70	0.04	0.86	0.03

Note. EQ-5D: EuroQol five-dimensional five-level(EQ-5D-5L).; Std. Err.: Standard error of the mean.

Table 4. Hospital Costs of the Surgical Method in Patients With Urinary Incontinence

Variable	Value (USD)
Mean	1,436.20
Median	1,467.71
Minimum	90.39
Maximum	4,297.09
Trimmed mean (10%)	1,425.36
Trimmed mean (20%)	1,428.87
Trimmed mean (30%)	1,432.62

Table 5. Findings of the Short-Term Cost-Utility Analysis of the Surgery Intervention Compared to Radiofrequency in Patients With Urinary Incontinence

	Radiofrequency	Surgery
Cost (USD)	622.52	2,200.41
Incremental costs (USD)		1,577.89
QALYs	0.35	0.483
Incremental QALYs	-	0.124
ACER (USD/QALY)	1,778.64	4,555.72
ICER (USD)		12,724.93

Note. QALY: Quality-adjusted life years; ACER: Average Cost-Effectiveness Ratio; ICER: Incremental cost-effectiveness ratio.

significantly lower than the cost of the surgical method (USD 2,200.41). However, the surgical method was associated with an average increase of 0.124 QALYs, reflecting the difference in QALYs between the surgery and RF groups over the same time horizon. The ICER for surgery compared to RF was estimated at USD 12,724.93, which is below the cost-effectiveness threshold in Iran, indicating that surgery is cost-effective compared to the RF method in the treatment of women with UI in Iran (Table 5).

4. Discussion

Given the significant impact of UI on healthcare costs, it is crucial to make evidence-based decisions regarding which interventions should be funded to ensure that resources are allocated in the most efficient manner. There are various treatment options with differing effectiveness for treating UI in women. However, despite the availability of treatment options, no comparative evaluation has so far been conducted between surgical methods and the new RF technology. Evaluating the cost-effectiveness of different treatment methods for UI, especially in countries with limited financial resources, is of paramount importance. This study attempted to economically compare surgical repair and RF in the short-term time horizon.

Assessing the effectiveness of interventions based on objective results, such as pad weight and bladder volume, for determining the severity of UI is time-consuming and not cost-effective. Therefore, self-reported questionnaires serve as a suitable tool for recording information in these patients since they evaluate both the severity of symptoms and QOL. In this study, using the PRAFAB questionnaire, only a small difference in the health status of patients was observed in different treatment groups. The overall score of the questionnaire in the surgery group was 14.5 before treatment and 12.15 in the RF group. The surgical intervention reduced the total questionnaire score by 6.1, while the RF intervention decreased the total score by 5.73. Both interventions could reduce the total questionnaire score similarly. Hence, despite the difference in baseline scores, which is related to differences in the severity and symptoms of the disease in the two comparison groups, the effectiveness of each intervention was reported to be almost the same. The surgical intervention reduced the PRAFAB questionnaire score by 0.37 more.

In this study, the utility weight of patients before the surgery was 0.21, and the utility weight of patients before RF was 0.50. However, in a review of studies on the QOL of patients with UI, the utility weight of people with UI was reported to be 0.71 (17, 18). It should be noted that many factors (e.g., the economic and social status of individuals in the society and the health system) affect the QOL of patients. Part of the differences is due to age,

average duration of the disease, and the prevalence of complications. Moreover, due to the shame associated with the disease, many individuals do not seek treatment until severe complications arise. In this study, age was a variable that had an inverse effect on the health status of patients. Nonetheless, education level and employment status were factors influencing the QOL of patients, as they sought treatment sooner. However, the analysis of HRQOL demonstrated that surgery was associated with an average increase of 0.124 QALYs compared to the RF method, suggesting that surgery may have a greater impact on improving patients' QOL.

The results of the Pearson test in both the surgical and RF intervention groups confirmed a significant correlation between the utility and the severity of incontinence, indicating that after the therapeutic intervention, with a reduction in the severity of UI, the utility weight of the patients improved, and this relationship was significant.

One of the key highlights was the significant difference in costs between the RF and surgical methods. The average cost of the RF method was about USD 622, while that of the surgical method reached more than USD 2,200. This significant difference in costs, especially for health systems with limited resources, can be crucial. It is noteworthy that the RF method, with its lower costs, can provide access to treatment for a larger number of patients while placing less financial burden on the healthcare system.

However, the ICER for surgery compared to RF was estimated to be USD 12,724, which is below the cost-effectiveness threshold in Iran, implying that despite higher costs, surgery is economically justified in the short term as well.

To the best of our knowledge, the economic evaluation conducted in this study has been the first evaluation of the RF intervention compared to the surgical intervention to date. One of the strengths of this study is the collection of RF technique samples from various public and private centers. In addition, this approach allows for the evaluation of diverse patient preferences, leading to more robust conclusions about the effectiveness and efficiency of this method.

A major limitation of this study was the relatively short follow-up period of only three months. We acknowledge that both surgical and RF interventions may demonstrate different patterns of effectiveness, recurrence, and associated costs over longer periods. However, due to financial and time constraints and difficulties in maintaining long-term follow-ups and based on consultation with clinical specialists, three months were considered to be the minimum feasible horizon to evaluate short-term outcomes in this context. Therefore, our cost-effectiveness findings should be interpreted with caution as short-term results, and further research with extended follow-ups and health economic modeling is essential to provide more robust evidence.

Another limitation of this study was the novelty of the RF method, which has not been studied as extensively as surgical interventions. There is insufficient long-term evidence on the effectiveness of RF devices, with only short-term success reported in limited studies. In addition, due to financial, economic, and political constraints in Iran, the use of standard FDA-approved devices was not feasible, and instead the Madame device was used, which, while technically capable, does not have health technology assement (HTA) approval in the Iranian health system. This factor may have further affected the generalizability of our findings.

Imbalance in baseline utility scores, which were lower in the surgery group compared to the RF group, was another limitation of study. Considering that our economic evaluation was primarily based on changes in utility and QALY gains, this difference did not alter the approach of our analysis. Nevertheless, baseline differences may affect direct comparability. Accordingly, future studies should consider using analysis of covariance or regression-based adjustments to account for this imbalance and strengthen the robustness of the findings.

5. Conclusion

The results of this study revealed that surgical treatment is a more effective intervention. It was also found that, despite higher costs, it is a cost-effective strategy in short-term for managing UI in Iran. Nevertheless, both RF and surgical methods have their own strengths and weaknesses. The final choice between these two methods should be based on individual patient characteristics and available healthcare resources. The results of this study can serve as an important basis for policymakers and healthcare providers in selecting and implementing the most effective and cost-effective treatment methods. However, to make a definitive decision regarding the effectiveness and cost-effectiveness of RF compared to surgery, further research and modelling with long-term evidences are necessary. Ultimately, the primary goal should be to improve the QOL for patients, considering the specific conditions and needs of each individual.

Nonetheless, our conclusions are limited to the three-month time horizon, and baseline differences between groups should also be taken into consideration. Finally, future studies with longer follow-ups and health economic modeling are required to provide a comprehensive picture of the long-term effectiveness and cost-effectiveness of these interventions.

Authors' Contribution

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Competing Interests

The authors declare that the research was conducted in the absence of any commercial or financial relationships.

Consent for Publication
Not applicable.

Data Availability Statement
All the data used in this study are reported within itself, and the main references are cited as well.

Ethical Approval and Consent to Participate
The study was approved by the Research Ethics Committees of the School of Public Health and Safety, Shahid Beheshti University of Medical Sciences (IR.SBMU.SME.REC.1402.024). Informed consent was also obtained from the participants.

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