Annales Africaines de Médecine
Article original

Determinants of Urinary Incontinence using IIQ-7 and UDI-6 in pregnant women: a case series in hospital setting in Kinshasa

Déterminants de l'Incontinence urinaire à l'aide de l'IIQ-7 et de l'UDI-6 chez les femmes enceintes : une série des cas en milieu hospitalier de Kinshasa

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Summary
Context and objective. Little is known about urinary incontinence (UI) in pregnant women in Sub-Saharan Africa. The present study aimed at describing clinical profile and assessing the determinants of UI in pregnant women. *Methods.* This was an analytical case series study consisting of all pregnant women seen in consultation in 3 medical formations in Kinshasa from June 2020 to May 2021. The selected women answered 2 UI assessment questionnaires: the Incontinence Impact Question-7 (IIQ-7) and the Urinary Distress Inventory-6 (UDI-6). *Results*. One thousand fifteen women were interviewed. The average age was 28.9 ± 6.6 years, the age group of 20-29 years was the most represented. The women's UDI-6 score increased significantly with age (p=0.001). The factors leading to severe disability were the university study level (p<0.001), multigestation (p=0.026), smoking (p<0.001), physical inactivity (p<0.001), obesity (p=0.008), infection (p<0.001), chronic cough (p=0.020), twin pregnancy (p=0.027), pelvic surgery (p<0.001), macrosomia (p<0.001) and UI (p<0.001). *Conclusion.* Urinary incontinence is observed at a high rate in pregnant women, characterized by an increase with age. It is marked by several associated factors (smoking, multiparity, and alcoholism, multigest)
Keywords: incontinence-multigestitis , multiparity, smoking
https://dx.doi.org/10.4314/aamed.v16i3.3

Received: March 24th, 2023
Accepted: May 14th, 2023

Résumé
Contexte et objectif. On sait peu de choses sur l'incontinence urinaire (IU) chez les femmes enceintes en Afrique subsaharienne. La présente étude a visé à décrire le profil clinique et à évaluer les déterminants de l'IU chez les femmes enceintes. *Méthodes*. Il s'agissait d'une série analytique des cas. La population étudiée était constituée de toutes les femmes enceintes vues en consultation dans 3 formations médicales de Kinshasa de Juin 2020 à Mai 2021. Après enquête, toutes ces femmes ont répondu aux questionnaires IIQ-7 et UDI-6. *Résultats.* 1015 femmes ont été interrogées. L'âge moyen était de 28,9 ± 6,6 ans, la tranche d'âge 20-29 ans était la plus représentée. Le score UDI-6 des femmes augmentait significativement avec l'âge (p=0,001). Les facteurs de handicap sévère étaient le niveau d'étude universitaire (p<0.001), la multigestation (p=0.026), le tabagisme (p<0.001), la sédentarité (p<0.001), l'obésité (p=0.008), l'infection (p<0.001), la toux chronique (p=0.020), la grossesse gémellaire (p=0.027), la chirurgie pelvienne (p<0.001), la macrosomie (p<0.001) et l'IU (p<0.001). *Conclusion*. L'incontinence urinaire est observée à un taux élevé chez les femmes enceintes, caractérisée par une augmentation avec l'âge. Elle est marquée par plusieurs facteurs associés liés au mode de vie de la femme elle-même (alcoolisme et tabagisme) et aux multiples grossesses.
Mots-clés : incontinence-multigestite, multiparité, tabagisme
https://dx.doi.org/10.4314/aamed.v16i3.3

Reçu le 24 mars 2023
Accepté le 14 mai 2023

Introduction

Urinary incontinence (UI) is an objectively demonstrable involuntary loss of urine constituting a social or hygiene problem. It is a deficiency, which can be the basis of a variable discomfort depending on the individuals and the societies in which they practice their activities (1). For women, it is a major public health problem. In the Democratic Republic of the Congo (DRC), a relatively recent report on UI in women noted an annual hospital frequency of 1.3% (23/1813 patients) (2). Another recent study of UI in young women in DRC revealed a high frequency of this entity in both urban and rural settings. In addition, UI has been associated with factors such as age between 14 and 17 years old, anxiety and urinary tract infection (3). As a part of standardization according to International Continence Society (ICS), two UI assessment questionnaires, originally in English (Incontinence Impact Question-7, IIQ-7 and Urinary Distress Inventory-6 score, UDI-6)] have been translated in 2 Congolese languages (Lingala and Kikongo) (4).

ICS epidemiological data reveal that UI prevalence range is 5% to 69 % (5). The various prevalence rates were reported according to perception, methodology and cultural aspects. UI prevalence measures may vary depending on the type of questionnaire used (6). Several risk factors have been noted: age, obesity and adiposity, parity, pregnancy and mode of delivery, menopause, hysterectomy, smoking, physical exercise, comorbidities (diabetes, urinary tract infections, intellectual disability, ischemic heart disease) (7). Data on UI in pregnant women are not correctly described in sub-Saharan areas, less so in the DRC. Our objectives are to characterize pregnant women with UI on a socio-demographic level in a hospital environment in Kinshasa and to determine the clinical characteristics as well as the factors associated with this entity using the IIQ-7 and UDI-6 questionnaires.

Methods

Study Type

An analytical case series study was conducted in Kinshasa, DRC.

Setting and study period

The study was carried out in the 3 following hospitals: Central Military Hospital (HMC), the Sino Congolese Friendship Hospital (HASC) and Kintambo Maternity Hospital (MK) and the surveys covered the period from June 2020 to May 2021.

Sampling

Study population

All pregnant women received in surgery, gynecology and obstetrics consultations in the 3 hospitals during the study period. Women were selected to meet the specific needs of this study hypothesis.

Sample size

The sample size for this study was probabilistic and was calculated from Fisher's formula:

$n \geq \frac{Z^2 x(p)(1-p)}{d^2}$, where n = Sample size, z = 1.96 (confidence coefficient), p = previous prevalence, d = 0.05 (margin of error or range of imprecision reflecting the desired degree of absolute precision).

In the Congolese population, the UI prevalence was 25.6 % according to Nako *et al.* (3).

The calculated sample size was $n \geq (1.96)^2 \times 0.256 \times 0.744/(0.05)^2 = 293$. By incorporating the 10% of non-respondents, the number of women to be interviewed rose to 322. To further increase the power of the test, 1015 subjects were finally interviewed.

Sampling technique

The women were recruited at 3 degrees. In the first degree, 9 hospitals in three districts of the city of Kinshasa were chosen in a reasonable way. The second-degree sampling procedure concerned the choice of 3 randomly drawn hospitals. In the third degree, the women were selected by systematic survey during consultations in Surgery and Gynecology units and after obtaining their consent to participate in the study.

Selection criteria

a) Inclusion criteria

Any pregnant woman who was at least 18 years old and freely agreed in a written or oral way to participate in the study was included.

b) Non-inclusion criteria

Pregnant women known with mental disorders and those in a state of unconsciousness were not concerned by these surveys. Pregnant women who did not answer two-thirds of the questionnaire questions during the survey were excluded from the study.

Data collection

Investigator training

The development of this work required several experts' assistance, in particular medical specialists, general practitioners and biostatistics experts brought together in a well-organized research team.

The investigator training was carried out in one session before the data collection.

Data collection methods

The data collection methods were based on the semi-structured face-to-face interviews. A standard questionnaire containing a number of themes was developed and submitted to the respondent. The interviewer lets the respondent answer in the order that suits him, trying to refocus the interview on the topics that interest him, if necessary, and to ask questions that are not raised by the respondent. These interviews were entirely anonymous and confidential; the participants were informed of the scientific nature of this study and of the respect of deontological and ethical rules. Participants confirmed their agreement by signing a consent form.

Variables of interest

The interest variables were:

- Socio-demographic characteristics including age, education level and medical training;
- Clinical characteristics and morbid history: gynecological identity (PGA), weight, height, tobacco consumption, alcohol, infection, constipation, physical activity, chronic cough and pelvic surgery.
- Factors favoring UI: cold, cough, defecation, coffee, sealing, alcohol.
- UDI-6 and IIQ-7 scores variables.

Concepts and operational definitions

The UI diagnosis was made on basis of UI questionnaire.

6 questions formed the basis of the diagnosis grouped in the UDI-6 form. Thus, taking into account the total obtained from the UDI-6 score, UI was categorized in terms of severity into the 4 following stages:

-score between 0-2: minimal incontinence
- score between 3-6: moderate incontinence
- score between 7-9: severe incontinence
- Score ≥ 10: very severe incontinence

Quality of life was assessed using the IIQ-7 score. As for the UDI-6 score, the IIQ-7 sum score made it possible to classify the women into 3 groups:

- low risk of handicap if the score is 0-2
- moderate risk of handicap if the score is 3-9
- risk of severe disability if the score ≥10

Statistical analysis

After data collection; an initial quality control was carried out in the field to ensure completeness, data accuracy and reliability. A second consistency check of each sheet was carried out to report corrections to certain inconsistencies noted in order to guarantee the results validity.

The data processing was done in several stages: questionnaire manual analysis, entry, purification, encoding on Excel 2010 as well as analyzes that were carried out on IBM SPSS for Windows version 22.0. We used multiple linear regression and logistic regression analysis to search determinants of UDI-6 score and UI, respectively. Data presentation was made in tables and figures form.

Ethical considerations

Before the questionnaire form was handed out to the participants, each interviewer sought informed consent from the person to be surveyed after a brief study of explanation objectives.

The respondent confidentiality was guaranteed because no personal information that could link the respondent to his data was disclosed. There were no direct benefits from the study participation, but the study results will allow researchers in DRC to implement evidence-based interventions to prevent UI.

Results

A total of 1015 women were questioned on the UI questionnaire. General characteristics of population studied are depicted in table 1. Their average age was 28.9 ± 6.6 years; the age group of 20-29 years was the most represented with 45% of cases, most women came from the HMC (44.3 %) and had mainly secondary school level (48.1 %). Median parity and gestility were 2 (1-3) and 3 (2-4), respectively. The majority of women were pauciparous (35.9 %) and 2nd-3rd parous (43.4%). Their weight, height and average BMI were respectively 74.4 ± 12.2 kg, 1.60 ± 0.09 m and 29.1 ± 5.3 kg/m^2; 40.5 % were overweight, 5.6 % and 38 .4 % took tobacco and alcohol respectively. Only 28.2 % practiced physical activity and 45% had undergone pelvic surgery.

Table 1. General characteristics of pregnant women with or without UI

Variables	No UI n=348	UI n=667	P
Age (years old)			**0.001**
<20	43 (12.4)	49 (7.3)	
20-29	171 (49.1)	286 (42.9)	
30-39	121 (34.8)	279 (41.8)	
≥40	13 (3.7)	53 (7.9)	
Educational level			**<0.001**
Primary	79 (22.7)	71 (10,6)	
Secondary	170 (48.9)	318 (47.7)	
University	99 (28.4)	278 (41.7)	
BMI			0.068
Normal weight	64 (18.4)	152 (22.8)	
Overweight	149 (42.8)	239 (35.8)	
Obesity	135 (38.8)	276 (41.4)	
Parity			**0.009**
Nulliparous	73 (21.0)	145 (21.7)	
Primiparous	104 (29.9)	154 (23.1)	
Pauciparous	121 (34.8)	243 (36.4)	
Multiparous	50 (14.4)	125 (18.7)	
Gesture			**0.034**
Primigest	63 (18.1)	102 (15.3)	
2-3rd gesture	164 (47.1)	277 (41.5)	
Multigesture	121 (34.8)	288 (43.2)	
Twin pregnancy	39 (11.2)	51 (7.6)	**0.039**
Macrosomia	126 (36.2)	223 (33.4)	0.208
Tobacco	25 (7.2)	32 (4.8)	0.079
Alcohol	105 (30.2)	285 (42.7)	**<0.001**
Infection	313 (89.9)	558 (83.7)	**0.004**
Constipation	115 (33.0)	339 (50.8)	**<0.001**
Physical inactivity	186 (53.4)	543 (81.4)	**<0.001**
Chronic cough	38 (10.9)	49 (7.3)	0.059
Pelvic Surgery	118 (54.0)	269 (40.3)	**<0.001**

Among UI favoring factors, the majority were cough (60.3%), cold (47%) and defecation (38.3%).
The women's UDI-6 score was found to increase significantly with increasing age (p=0.001).
There was a positive and significant linear correlation between age and UDI-6 score. This correlation was 49 % (r=0.489).

In a multiple linear regression analysis, age, BMI and parity emerged as UDI-6 score independent determinants, explaining 44% of its variability.

The overall frequency of UI in pregnant women determined on the basis of IIQ-7 and UDI-6 questionnaires was 65.7 % (667 women with UI out of 1015 pregnant women). Regarding the score severity, the severe incontinence rate was 42.1%.

The UI frequency increased significantly with the women's age (p=0.001) from 53.3% in those under 20 years old to 80.3% in women over 40 years old.

The UI frequency was significantly higher in multigestures with a significant difference (p=0.033).

By comparing the subjects with UI and those without UI, we noted that the women with UI comprised a greater proportion of subjects aged 30-39, over 40, university level, multiparity, multigestation, pregnancy twins, alcohol consumption, infection, constipation, physical inactivity and pelvic surgery.

In logistic regression, univariate analysis demonstrated age ≥40 years, 30-39 years, high school, university level, multigest, alcohol consumption, physical inactivity, constipation, defecation and coffee consumption emerging as UI determinants.

After adjusting for all these variables in a multiple logistic regression, high school, university level, alcohol consumption, multi-gravity, physical inactivity, constipation and coffee consumption emerged as UI determinants.

The determinants of UI were presented in table 2.

According to the quality of life, the majority of women had moderate diability risk (53.7 %), followed by severe disability risk (35.7 %). The simple linear regression analysis showed a significant positive correlation between the IIQ-7 score and UDI-6 (figure 1).

This correlation was 58 % (r=0.577).

Table 2. Determinants of pregnant women Urinary incontinence using logistic regression analysis

	Univariate analysis		Multivariate analysis	
Variables	p	OR (CI 95 %)	P	aOR (CI 95 %)
Age (years old)				
<20		1		1
20-29	0.096	1.47 (0.94-2.31)	0.619	0.86 (0.49-1.54)
30-39	**0.003**	2.02 (1.28-3.21)	0.926	0.97 (0.51-1.85)
≥40	**0.001**	3.58 (1.72-7.44)	0.407	1.46 (0.60-3.60)
Education level				
Primary		1		1
Secondary	<0.001	2.08 (1.44-3.02	**0.002**	1.91 (1.27-2.87)
University	<0.001	3,12 (2,11-4.63)	**<0.001**	2.36 (1.52-3.67)
Alcohol				
No		1		1
Yes	<0.001	1.73 (1.31-2.27)	**0.022**	1.58 (1.05-1.91)
Overweight				
No		1		1
Yes	0.030	1.34 (1.03-1.75)	0.245	1.19 (0.89-1.60)
Gesture				
Primipara		1		1
2-3rd gesture	0.822	1.04 (0.72-1.51)	0.788	1.07 (0.67-1.70)
Multigesture	**0.006**	1.74 (1.01-2.15)	**0.009**	1.67 (1.10-2.87)
Physical inactivity				
No				1
Yes	**<0.001**	3.81 (2.86-5.08)	**<0.001**	2.80 (2.03-3.87)
Constipation				
No		1		1
Yes	**<0.001**	2.09 (1.60-2.74)	**0.005**	1.56 (1.14-2.15)
Defecation				
No		1		1
Yes	**<0.001**	1.92 (1.47-2.50)	0.376	1.15 (0.84-1.58)
Coffee				
No		1		1
Yes	**0.001**	1.61 (1.23-2.11)	**<0.001**	1.85 (1.37-2.49)

According to the quality of life, the majority of women had moderate disability risk (53.7 %), followed by severe disability risk (35.7%).

The simple linear regression analysis showed a significant positive correlation between the IIQ-7 score and UDI-6 (figure 1). This correlation was 58 % (r=0.577).

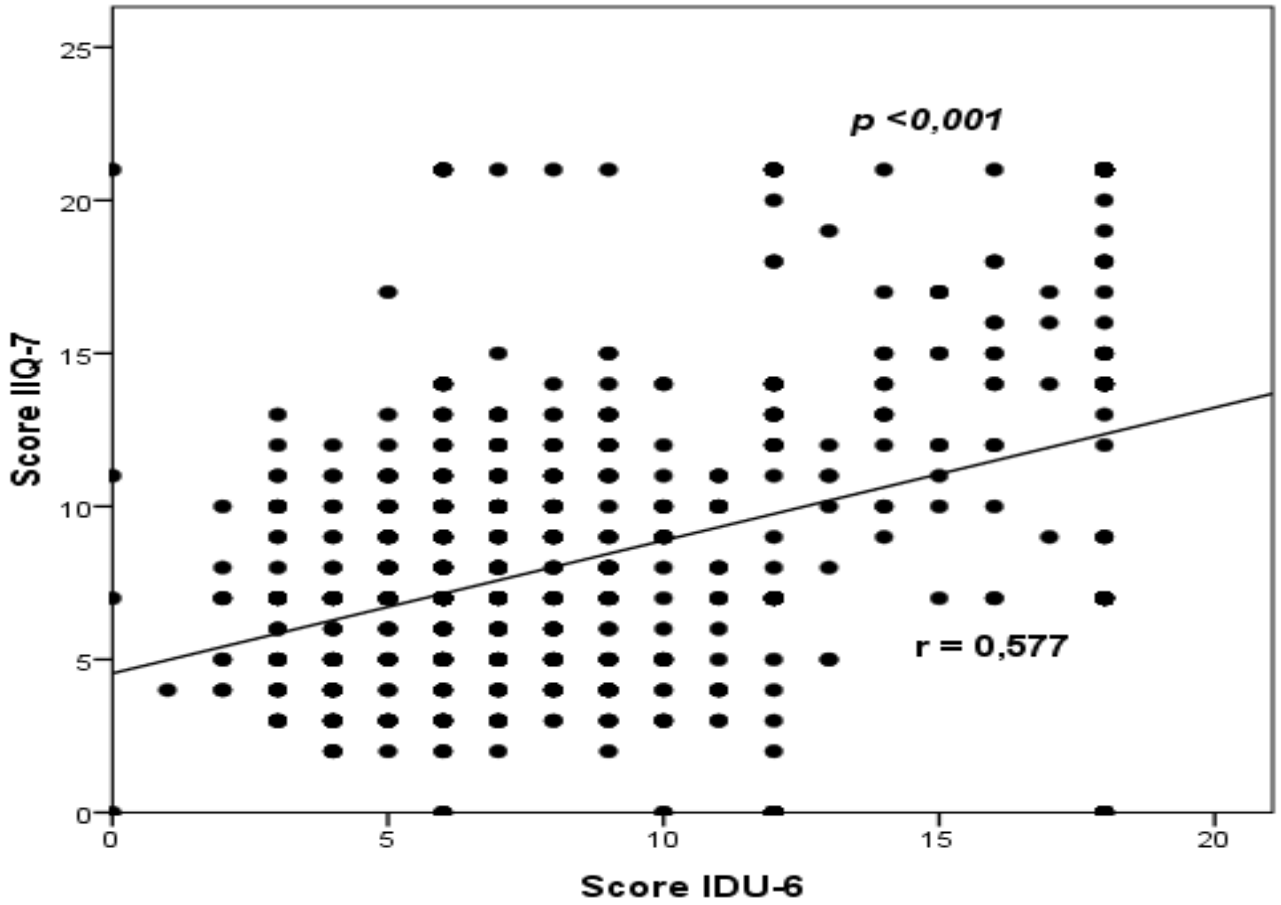

Figure 1. IIQ-7 and UDI-6 correlation in pregnant women

The factors leading to severe disability (table 3) were the university study level (p<0.001), multigestation (p=0.026), smoking (p<0.001), physical inactivity (p<0.001), obesity (p=0.008), infection (p<0.001), chronic cough (p=0.020), twin pregnancy (p=0.027), pelvic surgery (p<0.001), macrosomia (p<0.001) and UI (p<0.001).

Table 3. Factors associated with quality of life in pregnant women with UI

Variables	Low risk of disability	Moderate risk of disability	Risk of severe disability	P
Age (years old)				0.247
<20	6 (5.6)	60 (11.0)	26 (7.2)	
20-29	57 (52.8)	233 (42.8)	167 (46.1)	
30-39	38 (35.2)	217 (39.8)	145 (40.1)	
≥40	7 (6.5)	35 (6.4)	24 (6.6)	
Educational level				**<0.001**
Primary	8 (7.4)	109 (20.0)	33 (9.1)	
Secondary	50 (46.3)	284 (52.1)	154 (42.5)	
University	50 (46.3)	152 (27.9)	175 (48.3)	
Parity				0.179
Nulliparous	29 (26.9)	114 (20.9)	75 (20.7)	
Primiparous	31 (28.7)	141 (25.9)	86 (23.8)	
Pauciparous	39 (36.1)	188 (34.5)	137 (37.8)	
Multiparous	9 (8.3)	102 (18.7)	64 (17.7)	
Gesture				**0.026**
Primigeste	23 (21.3)	95 (17.4)	47 (13.0)	
2-3rd gesture	53 (49.1)	237 (43.5)	151 (41.7)	
Multigesture	32 (29.6)	213 (39.1)	164 (45.3)	
Tobacco	0	33 (6.1)	24 (6.6)	**0.026**
Alcohol	38 (35.2)	174 (31.9)	178 (49.2)	**<0.001**
Physical inactivity	3 (2.8)	182 (33.4)	101 (27.9)	**<0.001**
Overweight	37 (34.3)	201 (36.9)	150 (41.4)	0.257
Obesity	33 (30.6)	243 (44.6)	145 (37.3)	**0.008**
Infection	68 (63.0)	498 (91.4)	305 (84.3)	**<0.001**
Constipation	50 (46.3)	250 (45.9)	154 (42.5)	0.578
Chronic cough	2 (1.9)	55 (10.1)	30 (8.3)	**0.020**
Pelvic surgery	24 (22.2)	269 (49.4)	164 (45.3)	**<0.001**
Twin pregnancy	3 (2.8)	52 (9.5)	35 (9.7)	**0.027**
Macrosomia	13 (12.0)	193 (35.4)	143 (39.5)	**<0.001**
UI				**<0.001**
No	10 (9.3)	274 (50.3)	64 (17.7)	
Yes	98 (90.7)	271 (49.7)	298 (82.3)	

Discussion

This study objective was to characterize UI pregnant women from a socio-demographic point of view and to determine associated factors as well as clinical characteristics associated with UI pregnant women through the use IIQ-7 and UDI-6. Thus, several observations were made in the characterization of UI in the pregnant women and are discussed in the following paragraphs.

Sociodemographic data

In the current Congolese society, women get married mainly after the end of their high school in urban areas. On the contrary, in rural areas women usually get married in a very young age at the beginning of adolescence, which was the case in the pre-colonial period. The high frequency of incontinent pregnant women around 20 to 29 age old is due to the high sexual activity and marriage during this life period. The high UI prevalence between 20 and 40 years old can be explained by the high pregnancy frequency during this period. Nako et *al*. (3) had reported a high UI frequency in 18-21-year group in their study of incontinence in young people.

Clinical data and UI determinants

Women who had several pregnancies had stress UI (SUI), mainly due to multiple compression between the developing foetus and surrounding maternal organs (8). Hormonal pregnancy disturbances as well as bladder compression by the gravid uterus lead to bladder hyperactivity, which could cause urge UI (UUI) or mixed UI (MUI) (9). Indeed, the women bladder neck proximal apparatus is weak compared to that of the man. The female bladder neck distal apparatus is very sensitive to external influences such as pelvic floor insufficiency and injury or denervation due to the childbirth. UI secondary to sphincter insufficiency is more common in women due to weak anatomical structure.

This sphincter incompetencis is also observed in young nulliparous girls. The woman's cervix is not well individualized with fibers essentially of longitudinal orientation. Damage to the sphincter or its innervation (in particular the pudendal nerve) by obstetric trauma reduces the effectiveness of this device, which contributes to SUI risk (10).

In the present study, the UI prevalence was 65.7 %. This observation is similar to those reported by Mason *et al.* with 59% (11) and Whitford *et al.* with 54.3 % (12). In a meta-analysis based on UI prevalence and/or incidence in pregnant women, 63 % of selected women presented with a SUI. The majority of these women had mild to moderate incontinence (13).

It should be noted that the UI increased especially in the second half of pregnancy. Viktrup in Denmark, in a prospective study compared the UI prevalence before and during pregnancy as well as after childbirth and found that the prevalence was 4% before the pregnancy, 32 % during the pregnancy and 7 % after childbirth (14). In addition, according to Fritel, UI increases during pregnancy (between the 1st and 3rd trimester) then decreases spontaneously in the 3 first months of the postpartum, a further increase is observed in the years following childbirth (15).

The high prevalence during the pregnancy is related to SUI given the mechanisms involved in this type of UI. However, the present study did not look at these types of UI separately. Future research could study the different types of UI by integrating urodynamic assessments.

In the present study, multiple births, twin pregnancies, smoking, overweight, etc. were the UI risk factors. These findings are in accordance with those in the literature showing that parity, pre-pregnancy UI, overweight, vaginal delivery (compared to cesarean section) are pregnancy-related risk factors of UI (16- 22).

The UDI-6 score increased with age in patients of the present study, reflecting a progressive physiological mechanism deterioration linked to UI and increasing age. Indeed, the urological distress inventory score (UDI-6) short form makes it possible to detect UI associated with proctological symptoms by evaluating the severity degree, pain and dysuria (23). As age advances, a progressive score deterioration is noted.

The very severe UI forms were noted at higher rates than the minimal forms, even the multigestures had UI at higher rates than primigravida. This is probably explained by sphincter mechanisms alteration during multiple pregnancies as well as pregnancy hormonal disturbances leading to hyperactivity during this period.

The pregnant women BMI was higher than the norms in the present study; indeed 2/5 of pregnant women with UI were obese. This can be caused by the pregnancy weight increase, especially in the last trimester.

Indeed, in 2016, the global report indicated that obesity prevalence increased from 3.2% in 1975 to

10.8 % in 2014 in men and 6.4 % to 10.4 % in women and in all ages especially in developed countries (24). High BMI in women was positively associated with UI in studies conducted in Ghana (25) and China (26). In case of weight loss, a decrease in UI has even been demonstrated (18). Future postpartum obese group evaluation would be useful to determine the risk to develop UI.

Correlation between UDI-6 and IIQ-7 score

To assess urinary incontinence impact, it is necessary to measure both the level of an individual's symptoms and the extent to which they affect their life. Questionnaires are widely used to assess outcomes in urogynecology and have been previously validated in Lingala and Kikongo in DRC (4).

Kerry Avery, Donovan, and Paul Abrams developed these questionnaires based on psychometric standards, construct and convergent validity, reliability, and adaptative sensitivity (27).

In the present study, a positive correlation was found between the IIQ-7 and the UDI-6 scores. This result can be explained by the fact that both questionnaires assess similar parameters.

Women's quality of life

The UI-associated factors such as educational level, multigestation, physical inactivity, smoking, obesity, chronic cough, pregnancy and pelvic surgery were the source of severe handicap to pregnant women in the present study. Age wasn't among these factors although Steward et al. has noted age association with UI (28). In all available studies, the age-specific incidence is relatively low in women under 40, but increases with age (29).

To summarize the present study, UI is a very common symptom during pregnancy, and its prevalence increases as the weeks of gestation progress. Among the UI types, SUI is the most common. The level of UI discomfort is assessed heterogeneously and is experienced as mild to moderate by pregnant women.

Limits, strengths and perspectives

During this study, there were no incontinence specification types (SUI, UUI, MUI).

Other limitations include patient self-reporting nature of the study (questionnaire), which could lead to bias in the present study results.

Nevertheless, this study has strengths: i) it is the first study having used international questionnaires in the Congolese language for Congolese pregnant women, ii) It studied characteristics, determinants and factors associated with UI in pregnant women, and iii) the robustness of multivariate analyses as well as the multiple regressions used.

In order to improve pregnant women quality of life, planification program containing physical activity could be installed to prevent urinary incontinence during pregnancy.

Conclusion

This is an analytical study using UDI-6 and IIQ-7 questionnaires to assess symptomatic and asymptomatic characteristics related to involuntary urine loss in pregnant women. This entity concerns women in active procreation period (20 to 39 years) and is more observed in paucipares, multigestures, overweight and obese women. The UDI-6 and IIQ-7 score have a positive correlation with age.

The independent determinants and associated factors involved in UI in pregnant women are age, BMI, parity, smoking, urinary tract infections, and twin pregnancy. Pregnant women should be encouraged to practice physical activity during pregnancy to prevent urinary incontinence and thus maintain the quality of life.

Conflict of interest

Authors declared no conflict of interest

Contribution for authors

Mathieu Nkumu Loposso initiated the study, contributed to the drafting of the manuscript and presented his results at the ICS congress. Mosolongo Yebe Tresor collected the data, participated in the writing of this manuscript and presented these results at the ACU 2022 congress. Dieudonne Molamba Moningo, Pablo Kuntima Diasama Diangenda, Augustin Monga Lembe Punga-Maole. They read, and made corrections to the manuscript. All authors read and approved the final and revised version of manuscript.

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Cite this paper as: Loposso MN, Mosolongo TY, Moningo DM, Diangenda PKD, Punga-Maole AML. Determinants of Urinary Incontinence using IIQ-7 and UDI-6 in pregnant women: a case series in a hospital setting in Kinshasa. *Ann Afr Med* 2023; **16** (3): e5166-e5177 https://dx.doi.org/10.4314/aamed.v16i3.3

Annales Africaines de Médecine
Article original

Gyneco obstetrical outcomes after abdominal myomectomy in a Congolese setting population, in the Democratic Republic of the Congo

Devenir gynécologique et obstétrical après myomectomie dans une population congolaise, en République démocratique du Congo

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Résumé

Contexte et objectifs. Bien que la myomectomie soit connue l'intervention la plus pratiquée en infertilité, les données sur son impact sur la conception sont fragmentaires. La présente étude avait pour objectif de décrire le profil clinique des patientes myomateux ayant consulté pour infertilité et le devenir post myomectomie. Méthodes. C'était une étude documentaire d'une série des patientes avec myome ayant subi une myomectomie aux Cliniques universitaires de Kinshasa et au Centre Médical Edith, entre janvier 1999 et décembre 2018. *Résultats.* La fréquence de myomectomie était de 45,4 %. Leur âge moyen était de 35,8 ± 5,3 ans. Après myomectomie, le taux de conception était de 16 % ; les primipares et les grandes multipares avaient 2 fois plus de chance de concevoir que les nullipares (OR 2,1 [IC 95% : 1,2 – 3,6] p=0,006) et (OR 1,5 [1,2 – 14,4] p=0,007). Comparée à celles qui n'avaient qu'un seul noyau, l'énucléation de 2, 3 et 4 à 10 noyaux conférerait une chance de conception respectivement de 5, 9 et 17 fois plus élevée (OR 5,1 [1,2 - 21,8] p = 0,025) (OR 9,2 [1,9 – 45,02] p = 0,006) (17,8 [4,7 - 66,7] p < 0,0001). Les patientes chez qui les noyaux avaient pesé entre 501 et 1000 grammes avaient 3 fois plus de chance de concevoir (OR 3,1 [1,8 – 5,3] p< 0,0001) que celles chez les myomes pesaient moins de 500 grammes. Les accouchements étaient réalisés par césarienne donnant des nouveau-nés vivants. *Conclusion*. La myomectomie améliore le taux de conception.

Mots-clés : Infertilité, Kinshasa, Myomectomie, Conception

Reçu le 10 novembre 2022, Accepté le 21 avril 2023

Summary

Context and objectives. Although myomectomy is still the most frequent surgery for infertility, data on its impact on pregnancy rate is scarce in Kinshasa, Democratic Republic of Congo (DRC). The present study aimed to describe the clinical profile and the outcome of patients after myomectomy in the context of infertility.

Methods. This was a retrospective serial cases study including patients that sought care for infertility and underwent myomectomy at the Kinshasa University Hospital and Edith Medical Center from January 1999 to December 2018.

Results. The frequency of myomectomies was 45.47 %. The mean age of the patients was 35.84 ± 5.32 years; the majority (67.5 %) was nulliparous. No significant relationship was noted between the number and weight of myomas with age. After myomectomy, the rate of conception was 16%; primiparous and large multiparas were twice more likely to conceive than nulliparas (OR 2.1385 [CI 95%: 1.2477 - 3.6653] p = 0.006) and (OR 1.5833 [1.232 - 14.467] p = 0.007).

Compared to those with one myoma, the removal of 2, 3 and 4 to 10 myomas was associated with 5, 9 and 18 times more chance to conceive (OR 5.1929 [CI 95%: 1.2333 - 21.8652] p = 0.025) (OR 9.2499 [1.900 - 45.0237] p = 0.006) (17.8147 [4.753 - 66.7658] p < 0.0001 respectively. Patients for whom myoma weighed between 501 and 1000 grams were 3 times more likely to conceive (OR 3.1388 [95% CI: 1.8326 - 5.3760] p = 0.000) than those with less than 500 grams. Births at term were perfomed by cesarean section. Conclusion. Myomectomy improves the rate of conception.

Keywords: Infertility, Kinshasa, Myomectomy, Conception

https://dx.doi.org/10.4314/aamed.v16i3.4

Received: November 10th, 2022
Accepted: April 21st, 2023

Introduction

The influence of uterine leiomyomas (ULM) on reproduction has been established by several studies; they are present in up to 30% in patients consulting for infertility (1-2). Uterine myoma impacts the fertility by compression of genital tract causing the distortion of the cavity, tubal obstruction, abnormal myometrium contractility and impairment of endometrium vascularization that can cause myometrium atrophy, ulceration and diffuse inflammatory reaction. Therefore, it is implicated in implantation failure and pregnancy loss. In addition, obstetrical complications of uterine myoma also are well-known: spontaneous abortions, premature deliveries, abnormal presentation and placentation, postpartum hemorrhages and sepsis (3). For those reason, according to the location (FIGO's classification) and the size of uterine myomas, some patients need to be managed medically and others surgically, mainly by myomectomy, i.e. laparoscopic or abdominal myomectomy. Abdominal Myomectomy, which is a surgical procedure to remove one or more myomas from the uterus, is one of the most frequent surgeries for infertility patients (4), especially in Sub-Saharan setting, where uterine myoma is highly prevalent (5). Myomas are frequently numerous and of large size, requiring abdominal myomectomy as treatment of choice. Uterine myomas are the most frequent gynecological tumors in the world in general, even more so in black women (1). Myomectomy increases clinical pregnancy rate by up to 68 % in previously infertile patients (6). Some studies such as that by Sangha et *al.* in America (Detroit) found that regardless of the technique used, myomectomy enabled a quarter of infertile patients to have a child (7). In Europe (France), Rakotomahenina et *al.* had found from 85 patients operated on for myomectomy, 40 (47%) became pregnant and 33 (38.8%) gave birth to a live newborn (8). In Asia (Korea), Kim et *al.* reported 16 % of infertile patients achieved pregnancy and had alive newborns (9).

carried their pregnancies and delivered at term (11).

However, some complications are associated with myomectomy during, per and post-surgery, namely: hemorrhagic shock, lesions of surrounding organs, synechiae, pelvic adhesions and death of the patients. In our setting, the frequency of those complications climbed up to 41.74 % (12).

Despite the importance of myoma in our area in regard of the evolution of the diagnosis equipment and protocols of management, little is known on the outcome of patients after myomectomy in the context of infertility in Kinshasa, Democratic Republic of Congo (DRC). The objectives of the present study were to describe clinical profile of patients who had undergone myomectomies for infertility care, and to determine the impact of myomectomy on pregnancy rate.

Methods

Nature, setting and Period

This was an analytic retrospective serial case study including the patients that sought care for infertility and undergone abdominal myomectomy in the Kinshasa University Hospital and Edith Medical Center from January 1999 to December 2018.

Sampling and selection criteria

Our sampling was exhaustive, consisting of 537 records of patients who underwent myomectomy during the study period. All files were for patients followed for infertility and operated on for myomes.

Variables of interest

Variables of interest were anamnestic and socio demographic (age of patients, parity, type and duration of infertility, medico-chirurgical history), clinical (BMI), paraclinical characteristics (Ultrasound, Hysterosalpingography and endometrium biopsies findings), number and weight of myomas, gynecological (getting pregnancy and lost pregnancies) and obstetrical (deliveries) outcomes.

In Senegal, during a period of 26 months, among the 79 patients operated on for myomas with desire to conceive, Niang et *al.* had found that 19 of them (25 %) were pregnant and 84.6 % delivered by cesarean section (10). In Gabon, Bang et *al.* had found that for a total of 67 cases of myomectomy

Statistical analyses

The Data were recorded in Microsoft Access® 2000 software and analyzed by Stata / IC 15.1 software. Quantitative variables were summarized as mean and standard deviation, and qualitative variables as proportion with their confidence intervals.

Pearson's Chi-Square Test was used for comparison of proportions and Logistic Regression to determine the strength of association between different variables.

The test was considered statistically significant for p-value less than 0.05.

The files were treated confidentially and the data base was accessible only to the research team.

Results

From a total of 5,975 patients who sought care for infertility, 1,181 (19.7 %) had a myomatous uterus among which 537 (45.47 %) had undergone abdominal myomectomy.

General characteristics of patients

Anamnestic, socio demographic, clinical and paraclinical characteristics of the patients were described on table 1.

The average age was 35.84 ± 5.32 years with extremes of 22 to 50 years. Half of them (50.85%) were above 35 years old.

The majority of patients were nulliparous (67 %).

The mean duration of infertility was 6.18 ± 1.29 years and 3/4 (73 %) of patients consulted after 3 to 5 years.

Eighteen percent (17.33 %) had undergone myomectomy in the past.

The average BMI was 27.35 ± 4.40kg/m²; most patients were overweight (47.06 %).

Ultrasound confirmed the presence of myomas and HSG revealed tubal obstruction in 37.76 % of patients.

Based on endometrium biopsy, 23.09 % of patients had an offset endometrium.

Table 1. Socio demographic, clinical and paraclinical characteristics of the patients

Variables	N	%	Mean± DS	Min	Max
Age/year (n=533)			35.84 ± 5.32	22	50
20 – 24	5	0.94			
25 – 29	88	16.51			
30 – 34	169	31.71			
35 – 39	165	30.96			
≥ 40	106	19.88			
Parity (n=521)				0	5
Nulliparous	352	67.56			
Primiparous	103	19.77			
Pauciparous	47	8.96			
Multiparous	19	3.65			
Duration of infertility/ years (n=412)			6.18 ± 1.29	1	25
1	48	11.65			
2	64	15.53			
3 – 5	151	36.65			
6 – 25	149	36.17			
History (n=525)					
Nothing	268	51.05			
Appendicectomy	76	14.48			
Kystectomy	18	3.43			
Appendicectomy and Kystectomy	47	8.95			
Myomectomy	91	17.33			
Abdominal emergencies	6	1.14			
Cesarian Section	7	1.33			
Synechia Cure	12	2.29			
BMI (Kg/m²) (n=272)			27.35 ± 4.40	16.33	33
< 18.5	4	1.59			
18.5 – 24.9	88	32.47			
25 – 29.9	132	48.38			
30 – 34.9	48	17.56			
Ultrasound (n=537)					
Myoma	537	100			
Hysterosalpingography (n=535)					
Normal	104	19.44			
Bilateral Tubal Obstruction	146	27.29			
Unilateral Tubal Obstruction	56	10.47			
Pelvic Adhesions	7	1.31			
Synichae	13	2.43			
Endometriosis suspicion	34	6.36			
Undone	175	32.71			
NOVAK (n=524)					
Compatible Secretory Endometrium	59	11.26			
Offset Endometrium	121	23.09			
Proliferative Endometrium	19	3.63			
Endometritis	10	1.91			
Undone	315	60.11			

Characteristics of myomas

Characteristics of myomatous were described on table 2. The average number of myomas was 8.10±3.64 years; the majority of patients (64.62%) had more than 4 myomas. The weight of all the myomas removed during myomectomy ranged from 100 to 3200 grams

with an average of 790.50 ± 59.89 grams. For ten percent (9.64%) of the patients, myomas weighed more than 1000 grams.

Table 2. Characteristics of myomatous

Variables	n	%	Mean ± DS	Min	Max
Number (n=237)			8.10±3.64	1	45
1	41	17.47			
2	28	11.79			
3	15	6.11			
4 – 7	46	19.21			
8 – 10	23	9.61			
11 – 15	49	20.53			
16 – 45	35	15.28			
Weight (grams) (n=529)			790.50 ± 59.89	100	3200
100 – 500	387	73.16			
501 – 1000	91	17.20			
1001 – 1500	39	7.37			
1501 – 3200	12	2.27			

Gyneco obstetrical outcomes after myomectomy

After myomectomy, 88 patients out of 537 (16.39 %) became pregnant of whom 65 gave birth (73%); the chance to conceive was reduced by ninety-five times for the patients above 41 years (OR 0.0588 [95% CI: 0.0075-0.4565] p = 0.007). Compared to nulliparous, the ones who had delivered at least once and grand-multiparous were twice more likely to conceive (OR 2.1385 [95% CI: 1.2477 - 3.6653] p = 0.006) (OR 1.5833 [95% CI: 1.232 - 14.467] p = 0.007).

Compared to the patients with one myoma, the ones from whom 2 myomas were extracted were 5 times more likely to conceive (OR 5.1929 [95% CI: 1.2333 - 21.8652] p = 0.025), those with 3 had 9 times (OR 9.2499 [95% CI: 1.900 - 45.0237] p = 0.006) and those with 4 to 10 nuclei had 18 times (17.8147 [95% CI: 4.753 - 66.7658] p = 0.000) (17.8147 [95% CI: 4.1728 – 76. 547] p < 0.0001).

Patients whose myomas weighed between 501 to 1000 grams had 3 times more chances to conceive than the ones with less than 500 grams (OR 3.1388 [95% CI: 1.8326 – 5.3760] p < 0.0001) (table 3).

Table 3. Association between clinical characteristics and myomas in univariate analysis

Variables	OR	IC 95 %	P
Age (years)			
20 – 24	1		
25 – 29	0.4999	0.0783 – 3.1898	0.463
30 – 34	0.3107	0.0496 – 1.9434	0.211
35 – 39	0.3333	0.0533 – 2.0829	0.240
≥40	0.0588	0.0075 – 0.4565	0.007
Parity			
Nulliparous	1		
Primiparous	2.1385	1.2477 – 3.6653	0.006
Pauciparous	1.9791	0.9140 – 4.285	0.083
Multiparous	1.1875	0.3334 – 4.2290	0.791
Grand-Multiparous	1.5833	1.232 – 14.467	0.007
Number of enucleated myomas			
1	1		
2	5.1929	1.2333 – 21.8652	0.025
3	9.2499	1.900 – 45.0237	0.006
4 – 7	17.8147	4.753 – 66.7658	0.000
8 – 10	17.8147	4.1728 – 76. 547	0.000
11 – 15	2.9210	0.7327 – 11.6438	0.129
16 – 45	3.6543	0.8863 – 15.0670	0.073
Weight (grams)			
<500	1		
501 – 1000	3.1388	1.8326 – 5.3760	0.000
1001 – 1500	2.1187	0.9483 – 4.7337	0.067
1501 – 3200	0.6420	0.1046 – 0.1915	0.675

Factors associated with conception following myomectomy in multivariate analysis

In multivariate analysis, after adjustment for other variables, primiparous and pauciparous had 4 times more chances to conceive (adjusted OR 4.3397 [95% CI: 1.4649 - 12.8562] p = 0.008) (aOR 4.0567 [95% CI %: 1.0896 - 15.1025] p = 0.037) than nulliparas; and those for whom myomectomy had removed between 2 and 3 myomas were respectively 7 times and 22 times more likely to conceive (aOR 7.3684 [95% CI: 1.0758 - 50.4663] p = 0.042) (aOR 22.0110 [95% CI: 3.9837 - 121.6149] p < 0.0001) (table 4).

Table 4. Variables associated with design in multivariate analysis.

Variables	Adjusted OR	IC 95 %	P
Age (years)			
< 25	1		
25 – 29	1.5132	0.1660 – 1.37941	0.713
30 – 34	1.2304	0.1623 – 9.3279	0.841
35 – 39	0.7228	0.8737 – 5.9793	0.763
≥40	0.07649	0.0056 – 1.0268	0.052
Parity			
Nulliparous	1		
Primiparous	4.3397	1.4649 – 12.8562	0.008

Pauciparous	4.0567	1.0896 – 15.1025	0.037
Multiparous	10.8421	0.8941 – 131.4618	0.061
Grand-multiparous	11.1616	0.3784 – 329.1918	0.162
BMI			
Overweight	0.4929	0.1967 – 1.2349	0.131
Obesity	0.6391	0.1994 – 2.0476	0.451
Surgery story			
Appendicectomy	0.9770	0.3468 – 2.7526	0.965
Kystectomy	1.7437	0.6208 – 4.8976	0.291
Myomectomy	0.5133	0.1287 – 2.0473	0.345
Number of myomas			
1	4.0058	0.6094 – 26.3323	0.149
2	7.3684	1.0758 – 50.4663	0.042
3	22.0110	3.9837 – 121.6149	0.000
≥4	4.4179	0.9261 – 21.0746	0.062
Weight of myoma			
501 – 1000	1.1411	0.4448 – 2.9276	0.784
1001 – 1500	0.8025	0.2235 – 2.8806	0.736

Outcome of pregnancy with BMI and characteristics of myomas

According to association between the BMI, the number and the weight of myomas, there were no significant associations (table 5).

Table 5. Pregnancy outcome with BMI and characteristics of myomas

Outcome	Abortion	Normal delivery	C/S with live newborns	Maternal Death	Ectopic Pregnacy	Uterine Rupture	p
BMI							0.793
Smalless	0.00	0.00	0.00	0.00	0.00	0.00	
Normal	11.54	26.92	46.15	15.38	0.00	0.00	
Overweight	12.50	30.00	45.00	5.00	2.50	5.00	
Obesity	10.00	30.00	60.00	0.00	0.00	0.00	
Myoma's Number							0.778
1 (n=2)	0.00	50.00	50.00	0.00	0.00	0.00	
2 (n=6)	33.33	50.00	16.67	0.00	0.00	0.00	
3 (n=6)	16.67	50.00	33.33	0.00	0.00	0.00	
4 (n=24)	0.00	33.33	62.50	0.00	0.00	4.17	
>4 (n=29)	6.90	27.59	55.17	3.45	3.45	3.45	
Myoma's Weight							0.424
1 – 500 (n=43)	16.28	32.56	39.53	6.98	2.33	2.33	
501 – 1000 (n=26)	7.69	30.77	57.69	3.85	0.00	0.00	
1001 – 1500 (n=8)	0.00	25.00	50.00	15.50	0.00	12.5	
1501 – 3200 (n=1)	100.00	0.00	0.00	0.00	0.00	0.00	

Discussion

Epidemiological aspects of myomectomy

In the current study, a fifth of patients (19.7 %) who sought care for infertility had a myomatous uterus; the frequency of myomectomies among women treated for infertility was estimated at 45.4 %. Average age was 35.84 ± 5.32 years with a half over 35 years. These findings are consistent with those in the same area by Ingala et *al* (13), and Mboloko et *al.* (11). The mean time elapsed before the consultation was 6.18 ± 1.29 years. These results are similar to those by Bang and *al* who found an average duration of infertility of 7.9 ± 2.9 years (9) and Niang with an average of 6 years (8).

ULM is a more frequent pathology among infertile and elderly patients. The relatively advanced age of our patients is justified by the long preparation for life, delayed marriage, delayed consultations and after seeking care to traditional care providers before consulting gynecologists. This may explain the gradual increase over time, of the average age of infertile patients in our environment (14).

Furthermore, myomectomy is a more frequent surgery among infertile women in subSaharan environment. Niang and *al.* (10) had found a myomectomy frequency of 58.8% with an average age of 37.2 years and duration of infertility of 6 years, Bang and *al.* (9) in Gabon a frequency of 66.3% and an average age of 34 years. Zhang et *al.* in China found a mean age of 30 ± 3.7 years (15) and Kikelomo and *al.* a mean age of 34.3 ± 5 years in Nigeria (16).

Clinical and paraclinical aspects

The operated patients had an average BMI of 27.35 ± 4.40 Kg / m². Therefore, the majority of patients were overweight and obese. Findings of Mboloko showed that the mean BMI of patients getting pregnant after infertility management without Assisted Reproductive Technology in a Low-Income Setting was 25.23 ± 4.3 and Obesity was more frequent; in comparison with the normoweighted group, the rate of conception was low in thinness category and decreased with the BMI above 30 kg/m^2 (17).

Paraclinical investigations of the patients had shown that in 49 % of patients, there were HSG abnormalities including tubal obstructions in 37.61 % of cases and the diagnosis of infection made in 10% of cases. This is in accordance with findings of Roux and Niang, respectively 42 and 44.4% of tubal obstructions (4, 8). As for the diagnosis of infections, Niang et *al.* found *Gardnerella vaginalis* and *Candida albicans* in 67 % of patients (8).

Myomectomy

During the myomectomy, 35% of the patients had more than 10 myomatous nuclei and 10% of the patients had myomas weighed more than 1,000 grams. This is in accordance with the known statement that the black sub-Saharan or African American people are more susceptible to grow myomas of high number and weight (1). Therefore, laparotomy for myomectomy is the first approach with its consequences in terms of long hospital stay and pre- and post-operative complications (17).

During the present study, nearly 6% of patients had presented complications, the most frequent of which were eventration (47%) followed by infection (43%) including parietal infection, pelvi peritonitis, adnexitis, infectious toxic, shock and hemoperitoneum; death occurred in 3% of cases.

Kikelomo et *al.* in Nigeria found that hemoperitoneum was the major complication in 28.8% (16). This confirms the reputation of myomectomy as being an operation punctuated by serious complications (18).

A significant association was noted between complications and myoma weights, in particular between eventration and myomas of weight varying between 501 and 1000 grams.

Within the limits of our results, we cannot explain them. However, in the contingency table, there are several cells with less than 5 statistical units, which affect the validity of this result.

Conception after myomectomy and pregnancy outcome

After myomectomy, 16 % of patients had conceived of whom 73 % gave birth. This is higher than the rate of Mboloko et *al.* in 2019 (9 %) in the same environment (19), but lower than that found by Roux (20%) in Paris (4), than that of Rakotomahenina (47.05 %) in Bordeaux in 2016 (6), than that of Zhang (50.3%) in Shanghai in

2012 (15). According Cassini ML (2006), myomectomy improves conception rates (20).

In the current study, most of patients were aged from 20 to 45 years. In comparison with younger patients (20 - 24 years), the patients over 41 had only 5% the chance to conceive after myomectomy. Furthermore, primiparous and multiparous had 4 times more chance to conceive than nulliparous after myomectomy. This indicates that having already given birth gave a better chance of conception after myomectomy in patients seeking care for infertility (6).

Removing two to 10 myomas was associated with a high chance of conception compared to one myoma. Normally, myomectomy for single, myoma means that it was too large and distorts the anatomy of uterus and its environment (uterus, tubes and ovaries). Likewise, for a number greater than 10 myomas, the risk of adhesions formation is great. This could explain the reduction in fertility in these situations.

Our study showed that almost half (45 %) had given birth by caesarean section with the main indications being a scarred uterus followed by placenta praevia. This cesarean section rate is similar to that found by Kim et *al.* (7) in Korea in 2013 and Rakotomahenina in France (6) but higher than that of Zhang (15).

The scarred uterus as the main indication was consistent with the current medicine protocols, to avoid any uterus rupture risk during childbirth.

Strenghts and weaknesses

1. Strengths

Our study is the first in our field to describe the future state of patients operated on for myoma in the context of infertility; The sample size and the study period allowed us to extend the understanding of the problem.

2. Weaknesses

This is a descriptive study that is observational.

Conclusion

The current study found that myomectomy is the most common surgical procedure for infertility patients, which are elderly, obese and consulting late. Removing myoma improves pregnancy rate. Post operative complications can occur at any time. The delivery being preferentially by caesarean section was performed for scarred uterus.

Conflict of interest

Authors declared they have no conflict of interest

Contribution for authors

Conception, drafted, performed statistical analysis, revised the paper: PSM, JEM
Collected data, interpreted results and revised the paper: EMI, ALM
All authors read and approved the final and revised version of the manuscript.

Acknowledgements

Authors thank all members of gynecology and obstetrics' department who participated to the collect of data.

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Cite this paper as: Mogwo PS, Mboloko JE, Ilunga EM, Mputu AL. Gynecoobstetrical outcomes after abdominal myomectomy in a Congolese setting population, in the Democratic Republic of the Congo. *Ann Afr Med* 2023; **16** (3): e5178-e5188.
https://dx.doi.org/10.4314/aamed.v16i3.4