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Original Research Article

Quality of the informed consent process in diabetic foot amputation surgery: a prospective multicenter study in Senegal

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ABSTRACT

Background: Informed consent represents a fundamental ethical and legal requirement in surgical practice, particularly in mutilating procedures such as lower-limb amputation for diabetic foot. In low-resource settings, several structural and sociocultural factors may limit the quality of the informed consent process.
Methods: A prospective descriptive and analytical multicenter study was conducted from April to December 2022 in three teaching hospitals in Dakar, Senegal. Adult patients hospitalized for surgical management of diabetic foot were included. Data were collected using structured questionnaires completed by physicians and patients to evaluate socio-demographic characteristics, clinical data, and the quality of the informed consent process. The perceived quality of informed consent was categorized as favorable (excellent or average) or unfavorable (poor). Statistical analysis was performed using the Chi-square test with a significance level set at $p<0.05$.
Results: A total of 109 patients were included with a mean age of 62.1±9.1 years. Most patients (92.7%) reported understanding their diagnosis. However, several deficiencies were identified in the consent process: insufficient information about complementary investigations (78.9%), prosthetic rehabilitation (61.5%), and lack of confidentiality during counselling (82.6%). Only 25.7% of patients reported complete satisfaction with the consent process. Interview duration longer than five minutes ($p<0.001$), clarity of information ($p<0.001$), physician empathy ($p<0.001$), and counselling conducted in a private consultation room ($p=0.001$) were significantly associated with a favorable perception of informed consent.
Conclusions: The informed consent process for diabetic foot amputation remains suboptimal despite a generally positive physician-patient relationship. Improving communication, ensuring confidentiality, and allocating sufficient consultation time may significantly enhance the quality of informed consent in surgical practice.

Keywords: Amputation, Diabetic foot, Informed consent, Medical ethics, Senegal, Surgery

INTRODUCTION

Diabetes mellitus is a major and growing public health problem in Sub-Saharan Africa, characterized by increasing prevalence and frequent late diagnosis. Diabetic foot complications are among the most severe consequences of the disease and remain the leading cause of non-traumatic lower-limb amputation in the region.[1,2] Lower-limb amputation is a major and irreversible surgical procedure associated with significant functional, psychological, and social consequences. In this context, obtaining valid informed consent before surgery is essential. Informed consent requires that patients receive clear and appropriate information regarding their diagnosis, treatment options, risks, and expected outcomes.[3] In Senegal, informed consent is regulated by

Law No. 2011-33 of December 14, 2011 establishing the Code of Medical Ethics, which recognizes the patient's right to clear, fair, and appropriate medical information regarding their condition and the proposed treatment.[4] However, several studies conducted in Sub-Saharan Africa have reported that patients often receive incomplete information before surgical procedures.[5,6] In addition, clinical experience in surgical departments in Dakar suggests that many patients who sign consent forms may not fully understand the implications of lower-limb amputation. Although the principles of informed consent are universally recognized, their practical implementation is influenced by cultural, socioeconomic, and healthcare system factors. Previous studies have highlighted challenges such as low literacy levels, cultural perceptions of medical authority, and structural constraints within healthcare systems.[5-7] However, few studies in West Africa have specifically evaluated the quality of the informed consent process in major surgical procedures. Therefore, the aim of this study was to evaluate the quality of the informed consent process in patients undergoing diabetic foot amputation and to identify factors associated with a favorable perception of informed consent in three tertiary hospitals in Dakar, Senegal.

METHODS

Study design and setting

This prospective descriptive and analytical study was conducted between April and December 2022 in three teaching hospitals in Dakar, Senegal: Aristide Le Dantec Teaching Hospital, Abass Ndao Teaching Hospital, and Idrissa Pouye General Teaching Hospital. These institutions manage a large proportion of complex diabetic foot cases in the city.

The study was conducted in accordance with the Declaration of Helsinki regarding the protection, safety, and respect of research participants. Written informed consent was obtained from all participants prior to their inclusion in the study.

All adult patients hospitalized for surgical management of diabetic foot during the study period were eligible for inclusion.

Inclusion criteria was age ≥18 years, diagnosis of diabetic foot, indication for surgical treatment, and agreement to participate in the study.

Exclusion criteria included refusal to participate, severe cognitive impairment, and inability to communicate effectively without an interpreter.

Data collection

Data were collected using a structured questionnaire specifically developed for this study and based on previous research evaluating informed consent practices in Africa.[7,8] The data collection instrument consisted of two complementary questionnaires: one completed by the healthcare provider and the other by the patient, aimed at assessing both clinical characteristics and the quality of the informed consent process.

The healthcare provider questionnaire included information on the patient's clinical presentation, the type of amputation performed, the duration and location of counselling, the presence of relatives during the consultation, and the need for translation.

The patient questionnaire assessed several aspects of the informed consent process, including the perceived duration of counselling, respect for confidentiality, physician empathy, clarity of explanations, understanding of the diagnosis, information regarding investigations, treatment, and prosthetic rehabilitation, as well as emotional reactions and overall satisfaction with the counselling process.

Interviews were conducted individually in French or the local language (Wolof) by trained physicians involved in the study. The questionnaire is provided as supplementary material.

Statistical analysis

Statistical analysis was performed using R software version 4.2.1. Continuous variables were expressed as mean±standard deviation, while categorical variables were presented as frequencies and percentages.

The primary outcome was the perceived quality of informed consent, which was categorized as favorable (excellent or average) or unfavorable (poor). Responses classified as "average" were grouped with "excellent" responses because they reflected overall acceptable patient satisfaction.

Associations between study variables and consent quality were assessed using Pearson's chi-square test or Fisher's exact test when appropriate. A p value <0.05 was considered statistically significant. Logistic regression analysis was not performed due to the limited sample size. The sample included all eligible patients during the study period and was considered adequate for exploratory analysis.

RESULTS

Population characteristics

A total of 109 consecutive patients meeting the inclusion criteria were included in the study. The sociodemographic characteristics of the study population are presented in Table 1.

Table 1: Sociodemographic characteristics of the study population (n=109).

Variables	Categories	N	%
Age (years)	Mean±SD	62.1±9.1	–
	Range	34-93	–
	61-70	49	44.9
Sex	Male	66	60.6
	Female	43	39.4
	Sex ratio (M/F)	1.43	–
Educational level	Illiterate	61	55.9
	Literate	48	44.1
Employment status	Unemployed	69	63.3
	Employed	40	36.7
Socioeconomic status	Low	74	67.9
	Moderate/high	35	32.1

Table 2: Factors associated with favorable perception of informed consent (univariate analysis, Chi-square test, n=109).

Factors	Categories	Total (N)	Favorable perception N (%)	P value
Interview duration	≤5 minutes	22	5 (22.7)	<0.001
	>5 minutes	87	65 (74.7)	
Perceived clarity of information	No	8	2 (25.0)	<0.001
	Yes	101	68 (67.3)	
Perceived physician empathy	No	1	0 (0)	<0.001
	Yes	108	70 (64.8)	
Location of counselling	Hospital ward	36	15 (41.7)	0.001
	Consultation office	73	55 (75.3)	
Education level	Illiterate	61	37 (60.7)	0.320
	Literate	48	33 (68.8)	
Socioeconomic status	Low	74	45 (60.8)	0.217
	Middle	35	25 (71.4)	

Clinical and therapeutic data

The main diagnosis at admission was gas gangrene, observed in 55 patients (50.5%). The most frequent surgical indication was below-knee amputation (73.4%). The mean duration of diabetic foot lesion progression prior to surgical consultation was 48.4±10.5 days. A previous history of amputation was reported in 15 patients (13.8%).

Evaluation of the informed consent process

Preoperative counselling was conducted by a Senegalese physician in 91.7% of cases, and translation into a local language was required in 8.3% of interviews. Counselling most frequently took place in a consultation office (67.0%), whereas 33.0% occurred in hospital wards, sometimes in the presence of other patients. The duration of counselling was generally short: 71.6% of interviews lasted 5-10 minutes, 20.1% lasted less than 5 minutes, and only 8.3% exceeded 10 minutes. Regarding relational aspects, physicians were perceived as empathetic by 108 patients (99.1%).

However, confidentiality during counselling was reported by only 19 patients (17.4%).

Comprehension and completeness of information

While 101 patients (92.7%) reported receiving clear information regarding their diagnosis, several gaps were identified in the information provided. Only 23 patients (21.1%) reported receiving explanations about complementary investigations. Information regarding orthopedic prosthetic fitting was explained to 42 patients (38.5%). Moreover, only 31 patients (28.4%) considered the information concerning surgical treatment and postoperative follow-up to be sufficiently detailed and clear.

Reactions and decision-making

The announcement of amputation frequently triggered emotional reactions. Ninety-three patients (85.3%) expressed immediate emotional distress, including crying, profound sadness, or silence. Only 13 patients (11.9%) asked additional questions following the consultation.

Factors associated with favorable perception of consent

Univariate analysis identified several factors significantly associated with a favorable perception of informed consent (Table 2). This included interview duration longer than five minutes ($p < 0.001$), clarity of information ($p<0.001$), perceived physician empathy ($p<0.001$), and counselling conducted in a private consultation office rather than in a hospital ward ($p=0.001$). In contrast, education level ($p=0.320$) and socioeconomic status ($p=0.217$) were not significantly associated with patients' perception of the quality of informed consent. Table 2 presents the detailed associations between counselling characteristics and favorable perception of informed consent.

DISCUSSION

The present study evaluated the quality of the informed consent process in patients undergoing diabetic foot amputation in three tertiary hospitals in Dakar. Our findings reveal important deficiencies in the completeness of information and in the conditions under which counselling is delivered, despite a generally positive perception of physician empathy. This apparent contrast highlights the tension between a traditional beneficence-based model of care and the principles of patient autonomy.[9,10] The informational gaps observed in our study- where the diagnosis was generally explained but the implications of investigations, therapeutic options, and rehabilitation were insufficiently addressed- suggest a predominantly paternalistic model of care. In such a model, physicians act according to what they perceive as the patient's best interest, sometimes limiting information considered too complex or distressing.[11,12] Although this approach may foster trust and reassurance, as suggested by the high perception of physician empathy, it may reduce informed consent to passive acceptance rather than active participation in decision-making.[12,13]

Our findings also illustrate inequalities in access to medical knowledge within the physician–patient relationship. These inequalities are reinforced by several contextual factors, including high illiteracy rates (55.9%), perceived medical urgency (gangrene in 50.5% of cases), and limited healthcare resources. The frequent lack of confidentiality, particularly when counselling was conducted in hospital wards, represents an important barrier to effective communication. Delivering sensitive information in a non-private environment may limit patient expression and participation in decision-making. The absence of association between education level and perceived consent quality suggests that these difficulties are mainly organizational and cultural rather than purely educational.

Short consultation times represented another important limitation. Most interviews lasted between 5 and 10 minutes, and our analysis demonstrated that consultations lasting more than five minutes were significantly associated with better patient perception of informed consent. This finding suggests that allocating additional time for patient counselling may represent a simple and effective strategy to improve consent quality in routine surgical practice.

Our findings are consistent with previous studies conducted in Sub-Saharan Africa that have reported difficulties in achieving effective informed consent in surgical settings.[6,7,13] This study also highlights the importance of cultural and linguistic adaptation, as better perception of informed consent was observed when counselling was conducted by a Senegalese physician with translation when necessary.

Despite some limitations, our findings have important practical implications. Improving informed consent requires not only better information delivery but also improvements in the organization of care. Ensuring confidentiality, allocating sufficient consultation time, and improving communication skills among healthcare providers may substantially improve the quality of informed consent. Overall, this study demonstrates that the informed consent process for diabetic foot amputation remains insufficiently structured despite a generally positive physician-patient relationship. Practical interventions such as illustrated information materials, culturally adapted explanations, and protected consultation time may help improve patient understanding and participation in decision-making in resource-limited settings.

Despite these limitations, our findings have important practical implications. Improving the informed consent process requires not only clearer and more comprehensive information but also better organization of care. Ensuring confidentiality during counselling, allocating sufficient time for patient discussions, and strengthening communication skills among healthcare providers may substantially enhance the quality of informed consent. Our results indicate that the informed consent process for diabetic foot amputation remains insufficiently structured despite generally positive physician-patient relationships. In resource-limited surgical settings, improving informed consent does not necessarily require complex interventions. Simple and feasible measures- such as ensuring privacy during counselling, providing culturally adapted explanations, and allocating protected consultation time- may significantly improve patient understanding, encourage active participation in surgical decision-making, and strengthen respect for patient autonomy.

This study has some limitations. First, the assessment of informed consent quality was based on patient perceptions and may therefore be subject to recall bias and social desirability bias. Second, the study was conducted in urban tertiary hospitals, which may limit the generalizability of the findings to rural healthcare settings. In addition, the relatively small sample size did not allow multivariate analysis, limiting the ability to control for potential

confounding factors. Future studies with larger sample sizes and the use of objective assessment tools, such as standardized knowledge tests, would provide a more comprehensive evaluation of the effectiveness of the informed consent process.

CONCLUSION

The informed consent process for diabetic foot amputation remains suboptimal in our setting despite generally positive physician-patient relationships. Significant gaps persist in the completeness of information, confidentiality of counselling, and the organizational conditions under which consent discussions take place. Simple and feasible measures- such as ensuring private counselling environments, allocating sufficient consultation time, and improving communication practices- may substantially enhance patient understanding and participation in surgical decision-making. Strengthening the informed consent process should therefore be considered a priority for improving ethical standards and patient-centered care in surgical practice in resource-limited settings.

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