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par

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TITRE

Chirurgie du mélanome cutané en un temps opératoire guidée par la mesure échographique préopératoire de l'épaisseur maximale : étude qualitative de la perception des patients

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En présence des enseignants et enseignantes
de cette Faculté,
de mes chers condisciples
et selon la tradition d'Hippocrate,
je promets et je jure d'être fidèle aux lois de l'honneur
et de la probité dans l'exercice de la Médecine.

Je donnerai mes soins gratuits aux indigents,
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LISTE DES ABREVIATIONS

COREQ	consolidated criteria for reporting qualitative research
HFUS	high-frequency ultrasonography
JPL	Jean-Pierre Lebeau
LM	Laurent Machet
ML	Margueritte Lim
US	ultrasonography
SSM	Superficial Spreading Melanoma
WLE	wide local excision
YM	Youssef Mourtada

INTRODUCTION GENERALE

Le mélanome cutané est l'un des cancers, avec le cancer du poumon chez les femmes, qui connaît la plus forte augmentation tous sexes confondus, atteignant 17922 nouveaux cas estimés en 2023 en France (1). Cette augmentation concerne principalement les tumeurs de plus faible épaisseur (inférieure ou égale à 1 mm) diagnostiquées à un stade précoce et dont le traitement repose sur l'exérèse chirurgicale (2).

Selon les recommandations actuelles, une stratégie en deux temps opératoires est préconisée : une première exérèse avec des marges courtes de 1 à 3 mm (3) puis une reprise élargie dont la taille est adaptée à l'épaisseur tumorale maximale mesurée en histologie (indice de Breslow). La Société Française de Dermatologie recommande des marges de 0,5 cm pour un mélanome *in situ* (ou intra-épidermique), 1 cm pour un mélanome < 1 mm, entre 1 et 2 cm pour un mélanome invasif ≤ 2 mm et 2 cm pour un mélanome > 2 mm (4). Les recommandations européennes en 2022 sont proches avec des marges de 0,5 cm pour un mélanome *in situ*, 1 cm pour un mélanome inférieur à 2 mm, et 2 cm pour un mélanome supérieur à 2 mm. Les marges de sécurité peuvent aller jusqu'à 1 cm pour les mélanomes *in situ* du visage (3). Dans certains cas, une biopsie cutanée partielle peut être réalisée sur une lésion suspecte étendue et lorsqu'une exérèse pourrait être délabrante. La biopsie partielle permet de confirmer le diagnostic de mélanome et d'estimer l'indice de Breslow avant de réaliser l'exérèse du mélanome avec les marges adaptées. Cependant, cette estimation peut être erronée si la biopsie partielle n'intéresse pas la partie la plus épaisse du mélanome.

L'échographie cutanée à haute fréquence (> 20 MHz) permet la visualisation des différentes couches de la peau ainsi que la mesure de l'épaisseur d'une lésion. Plusieurs études ont montré une bonne corrélation des mesures échographiques et histologiques de l'épaisseur des mélanomes (5–17) permettant une approche chirurgicale en un seul temps opératoire (6–

10,18,19) avec des marges chirurgicales d'emblée adaptées à la mesure de l'épaisseur échographique. Au sein de notre service, nous proposons depuis plus de 10 ans une chirurgie en un temps opératoire avec marges adaptées à l'épaisseur échographique aux patients ayant une lésion cliniquement évocatrice de mélanome, ou ayant un diagnostic histologique de mélanome posé sur une biopsie partielle (6).

Mais, cette stratégie comporte, rarement, des inconvénients (excès de diagnostic de malignité, marges chirurgicales en excès, ou insuffisantes nécessitant une deuxième intervention), et elle reste en dehors des recommandations. Pourtant, on peut supposer qu'une chirurgie en un seul temps opératoire comporte des avantages pour les patients. De plus, la majorité des patients atteints de mélanome souhaite jouer un rôle actif dans la stratégie thérapeutique (20). Aucune donnée n'existe concernant l'expérience des patients à l'égard de ces deux options chirurgicales (un ou deux temps opératoires).

Notre étude MELAPREOP explore la perception des patients sur la prise en charge opératoire de leur mélanome, guidée par la mesure de l'épaisseur échographique maximale permettant le choix d'une exérèse large en un seul temps opératoire (groupe A) ou, sans échographie cutanée préopératoire mais mesure de l'indice de Breslow et exérèse en 2 temps (groupe B). Comment les patients perçoivent-ils la proposition d'une chirurgie en un temps ou d'une chirurgie en deux temps opératoires pour traiter leur mélanome cutané primitif ? L'objectif de cette étude est de recueillir les préférences des patients dans le but d'améliorer la consultation préopératoire et ainsi aider médecins et patients dans la décision partagée du traitement chirurgical de leur mélanome.

L'article scientifique sera soumis pour publication dans la revue *British Journal of Dermatology*.

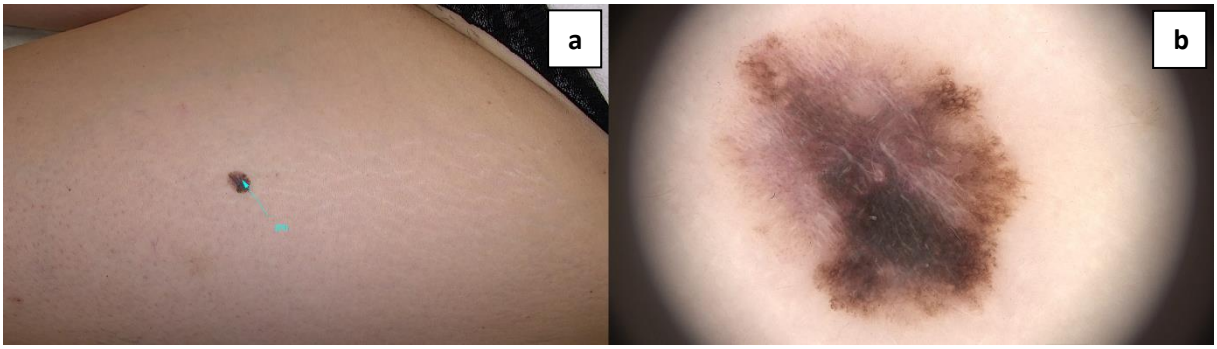

Figure 1. Mélanome cutané de la cuisse. (a) Photographie clinique et (b) dermoscopique

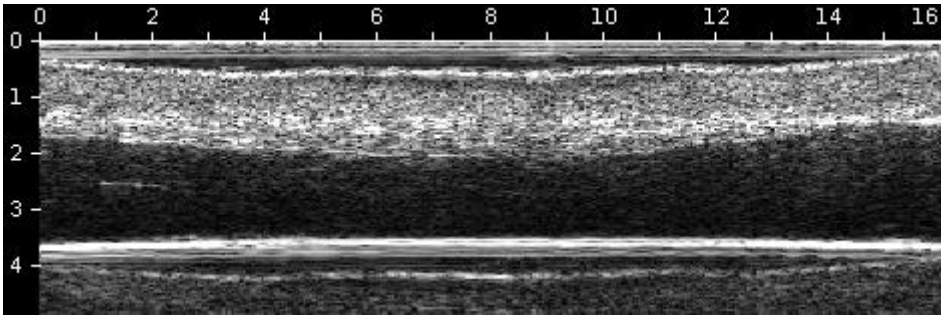

Figure 2. Mesure de l'épaisseur tumorale en échographie cutanée (25 MHz)

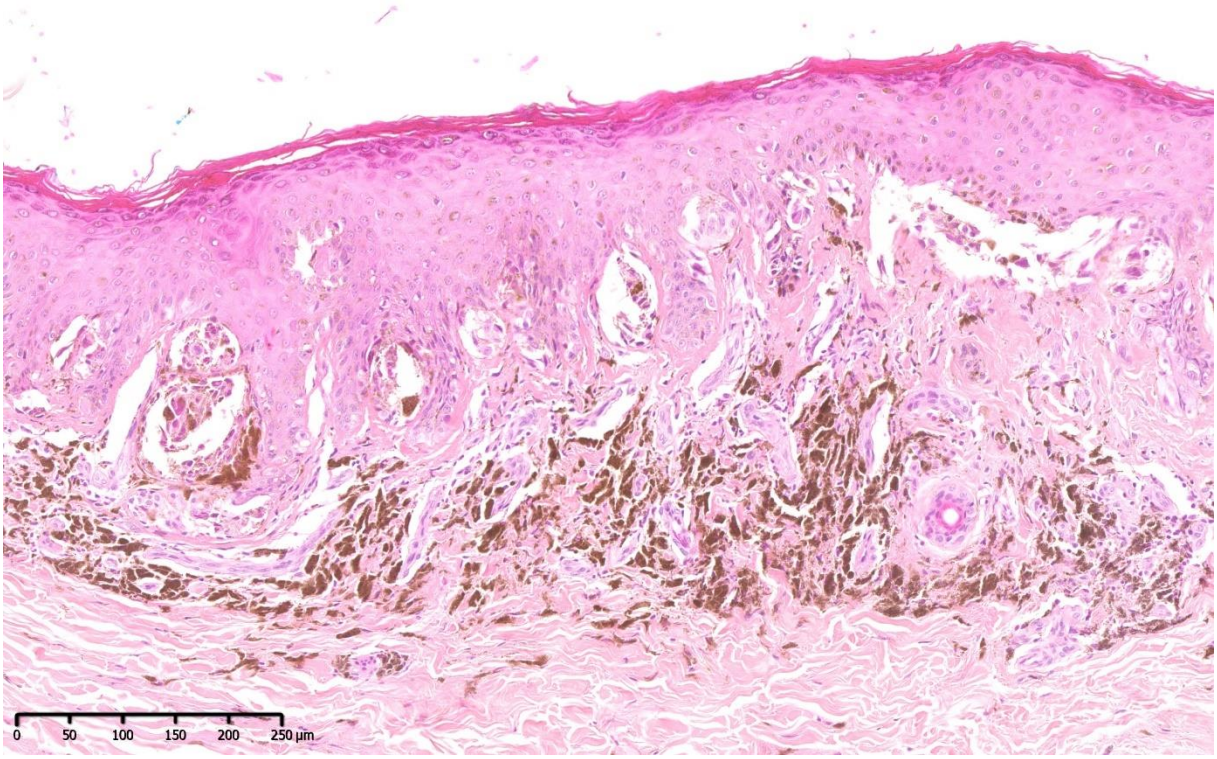

Figure 3. Analyse histologique du mélanome, type SSM, indice de Breslow 0,6 mm (coloration Hématoxyline-Phloxine-Safran, x200)

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RESUME EN FRANÇAIS

Chirurgie du mélanome cutané en un temps opératoire guidée par la mesure échographique préopératoire de l'épaisseur maximale : étude qualitative de la perception des patients

Introduction :
L'échographie cutanée haute résolution (> 20 MHz), permet la mesure préopératoire de l'épaisseur du mélanome cutané, bien corrélée avec l'épaisseur histologique (indice de Breslow). La chirurgie en 1 temps opératoire guidée par l'échographie cutanée est une nouvelle approche combinant le diagnostic et le traitement du mélanome en une seule intervention chirurgicale d'emblée avec des marges adéquates. Les avantages potentiels d'une telle stratégie pour les patients restent à explorer.

Objectif :
Explorer les perceptions des patients sur la proposition d'une chirurgie en 1 ou en 2 temps opératoires pour traiter leur mélanome cutané primitif.

Méthodes :
Nous avons mené une étude qualitative par entretiens individuels semi-directifs auprès de 2 groupes, entre juin 2022 et août 2023. Les patients du groupe A ont reçu la proposition d'une chirurgie en 1 ou 2 temps, après la pratique d'une échographie cutanée préopératoire. Les patients du groupe B ont été opérés en 2 temps (exérèse sans marge suivie d'une reprise chirurgicale), sans proposition préalable d'une chirurgie en 1 temps. Les entretiens ont été audio-enregistrés et analysés selon une approche inductive générale.

Résultats :
Vingt-et-un patients, 16 dans le groupe A et 5 dans le groupe B, ont été interrogés. Les patients du groupe A exprimaient une nette préférence pour une chirurgie en 1 temps opératoire. Ils appréciaient être associés à la décision chirurgicale et étaient rassurés par la mesure de l'épaisseur maximale échographique, malgré le diagnostic de mélanome. La communication des médecins sur les suites opératoires doit être améliorée. Les patients du groupe B sont également satisfaits de leur prise en charge, bien qu'ils auraient préféré une chirurgie en 1 seul temps si on leur en avait fait la proposition avant la première exérèse.

Conclusion :
La chirurgie en un temps peut être proposée aux patients après informations claires et complètes sur le diagnostic, le traitement et les suites opératoires lors de la consultation préopératoire. Mettre le patient au centre du processus décisionnel améliorerait la qualité des soins.

Mots clés : mélanome, marges d'exérèse, échographie cutanée, décision partagée, décision de traitement, recherche qualitative

ARTICLE EN ANGLAIS

Title: Exploring Patients' Perceptions of One-Step Surgery for Primary Cutaneous Melanoma: a qualitative study

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ABSTRACT

Background High-frequency ultrasonography (HFUS >20 MHz) has allowed for preoperative measurement of melanoma thickness and thus a one-step surgery strategy, a novel approach combining clinical diagnosis and treatment in a single surgical intervention. However, the potential benefits of one-step surgery to patients remain unexplored.

Objective To explore patients' perceptions of proposing one-step or two-step surgery for treating their primary cutaneous melanoma.

Participants and methods From June 2022 to August 2023, 2 dermatologists conducted in-depth individual interviews with patients who had undergone HFUS examination allowing the choice for one-step surgery (group A) and with patients who had had standard two-step surgery (group B). A semi-structured topic guide was used during the interviews, which were audio-recorded. Transcripts were coded and organized into themes and categories. A general inductive approach was used to guide sampling, data collection and analysis.

Results Interviews with 21 patients (age range 31-81 years) revealed five categories: (a) understanding the diagnosis, highlighting the significance of clear and comprehensive medical explanations; (b) personal factors considered in treatment decisions, including preferences for minimizing surgical procedures; (c) making choices, bearing responsibility, thus showcasing different levels of patient involvement in decision-making; (d) US reassurance emphasizing the role of medical reassurance and (e) patient satisfaction, discussing surgical outcomes and the decision-making process. Twenty of the 21 participants expressed a clear preference for one-step surgery, perceived as a pragmatic and fast surgical strategy while minimizing interventions.

Conclusions Our results emphasize the importance of patient-centered care. During the consultation, clear and comprehensible delivery of information about the diagnosis, treatment and post-operative outcomes can empower patients to make informed decisions that align with

their preferences and values to improve their quality of care. These insights can guide improved preoperative consultations and enhance shared decision-making between healthcare professionals and patients regarding melanoma treatment strategies.

Keywords: melanoma, margins of excision, high-frequency ultrasonography, shared decision-making, treatment decision making, qualitative research

CAPSULE SUMMARY

What is already known about this topic?

- Cutaneous melanoma tumors are excised with 0.5- to 2-cm safety margins according to the maximal thickness measured on histology slides (Breslow thickness). This approach usually requires 2 surgical steps: excisional biopsy and further re-excision according to histology thickness.
- Measuring the thickness of the tumor with high-resolution ultrasonography allows for removing the tumor in a single step with adequate margins in at least 82% of the cases in routine care.
- An in-depth understanding of how patients perceive the decision for one-step (or two-step) surgery for primary cutaneous melanoma is lacking.

What does this study add?

- Patients clearly expressed their preference for one-step surgery.
- Measurement of maximal tumor thickness at the first visit and medical explanations are reassuring to patients.
- Patients also appreciate being involved in the decision of one- or two-step surgery.

What are the clinical implications of this work?

- Patients are able to understand and choose between the 2 options.
- One-step surgery should be proposed to patients after they are given adequate information.
- Clear and comprehensible delivery of information can empower patients to make informed decisions that align with their preferences and values to improve their quality of care.

INTRODUCTION

One-step surgery for melanoma is a novel approach that aims to combine diagnosis and treatment, with appropriate surgical margins based on the measured tumor thickness, in a single surgical intervention. When melanoma is suspected, surgical excision with a 1- to 3-mm margin is recommended according to standard practice (1). Re-excision with or without sentinel lymph node biopsy is guided by the Breslow thickness. Following the French Society of Dermatology (2) and American Academy of Dermatology recommendations (3), the safety margins are 5 mm for *in situ* melanoma, 1 to 2 cm for Breslow thickness > 1 mm or *in situ* melanoma on the face, and 2 cm for Breslow thickness > 2 mm. The updated 2022 European recommendations are similar: 5 mm for *in situ* melanoma, 1 cm for thickness ≤ 2 mm, and 2 cm for thickness > 2 mm (1). Sometimes an incisional partial skin biopsy may be necessary to confirm the diagnosis when the melanoma is extensive. However, estimating Breslow thickness based on the biopsy may be inaccurate, especially if the thickest part of the tumor is not sampled.

High-frequency ultrasonography (HFUS), with a probe > 20 MHz, allows for measuring the maximal thickness of primary cutaneous melanoma tumors and shows good correlation with the Breslow thickness measured on histological slides (4–15). Therefore, HFUS could accurately guide surgical planning and be a valid option for one-step surgery (10–18). We have routinely offered one-step surgery guided by HFUS to patients, with low risk of excessive excision or inadequate excision requiring a second excision (17).

One study found that 80% of melanoma patients wanted an active role in treatment decisions (19). Shared decision-making in this situation is deemed appropriate as patients' preferences are sought in the context of multiple existing options (20). However, to our knowledge, no study has addressed the potential benefits for melanoma patients choosing one-step versus two-step surgery (excisional biopsy followed by re-excision). The main objective of this study was to explore patients' perceptions and experiences in deciding between one-step

and two-step surgery for melanoma treatment: how patients weighed the 2 options as well as their preferences and factors influencing their decision-making process. We aimed to gain an understanding of patients' perceptions to improve preoperative consultation and facilitate shared decision-making between physicians and patients regarding the surgical treatment of melanoma.

PARTICIPANTS AND METHODS

Study design

This was an exploratory qualitative study involving individual semi-structured interviews. It was conducted in accordance with the COREQ 32 qualitative research recommendations (21).

Study setting and selection of participants

Participants were referred after a first primary care consultation or directly recruited at the University Hospital Center of Tours within the dermatology, plastic surgery, and maxillofacial surgery departments. Inclusion criteria were age > 18 years with a sufficiently suspicious lesion or partial biopsy-proven cutaneous melanoma (group A) or previous two-step surgery (group B). Exclusion criteria were metastatic melanoma; non-cutaneous melanoma, such as mucous or ocular melanoma; and inability to give consent. Eligible participants were addressed to our dermatologic clinic. They were approached by a dermatologist of the medical team (LM or ML), and if they agreed, the dermatologist discussed the study with them. For group A, during the preoperative consultation, the dermatologist explained that excision could be performed in a single session after US examination of the skin. Surgical margins were guided by sonometric thickness. In case of a partial biopsy performed before referral, the maximum depth based on histology or US was used to determine the size of surgical margins. We used a 25- and 50-MHz probe with axial resolution 30 µm and lateral resolution 120 µm (Dermcup, Atys médical,

Soucieu-en-Jarrest, France). The imaging was performed by one of 2 trained operators (LM and YM) with more than 10 years of experience each. Patients could choose between one-step or the standard two-step surgical procedure. During a postoperative consultation, we informed patients of group B, those with previous two-step surgery, about the availability of the HFUS examination and the principle of one-step surgery. We asked them which surgical approach they would have preferred if given the choice.

We interviewed participants after their surgery. If non-participants such as a family member accompanying the patient were present during interviews, we asked them to intervene as little as possible during the interview.

To achieve maximal variation, we used a purposive sampling method to recruit participants who varied in sex, age, melanoma location, and time between the interview and last surgery.

Data collection

Interviews were held between June 2022 and August 2023 by two researchers (LM, male, senior dermatologist, and ML, female, dermatology resident) who were new to qualitative research methods. An interview guide with open-ended questions (**Appendix S1**) was developed to structure the interviews and was supervised by a general practitioner experienced in qualitative research (JPL). The main topics most relevant to a discussion of informed choice were addressed: melanoma diagnosis and treatment options, surgical decision-making, and experience with US examination. The interview guide was pilot-tested on one patient. None of the patients was known to the dermatologists. Researchers held the interviews in person in a consultation room at Tours hospital, except for 2 patients who were interviewed by telephone and one patient who was interviewed at home. Field notes were taken during interviews.

Data analysis

All interviews were audio-recorded and transcribed verbatim. Transcripts were de-identified to ensure confidentiality. We used a general inductive approach to data analysis (22,23). Two researchers (LM and ML) independently coded each verbatim. Initial coding was performed line by line from the verbatim. Differences between coders were resolved by discussion. Then codes were organized into themes and categories were identified. Data saturation was reached when no new codes arose from the interviews, and hence, recruitment was stopped after the 21st participant. Microsoft Word and Excel were used for coding and analysis.

Ethics statement

This research was approved by the Ethics Committee in Human Research of the Medical Faculty of Tours (no. 2022 027). Participants received an information sheet about the study, including a non-opposition document, and could contact the researcher LM by phone or email if they had further questions. All participants provided informed consent before study participation.

RESULTS

Study population

A total of 21 patients divided into group A (n = 16) and B (n = 5) were interviewed within 7 months of the final diagnosis (**Figure 1**). The mean age was 53.7±16.7 years (range 31-81). Participant characteristics are in **Table 1**. The mean interview duration was 21 min (range 9–48). No patient declined to participate in the study.

Synthesis and interpretation of the data

Five categories emerged from the analysis that provided insight into patients' experiences and perceptions of one-step surgery: (a) understanding the diagnosis; (b) personal factors considered in treatment decisions; (c) making choices, bearing responsibility; (d) US reassurance; and (e) patient satisfaction.

Understanding the diagnosis

Clear information from healthcare professionals: a valuable aid in the decision-making

Participants' responses revealed varying levels of clarity and comprehension regarding the diagnosis and surgical information provided by the dermatologist. Most participants understood their diagnosis and recalled receiving counseling from their physician who suggested one-step surgery as an appropriate treatment. These explanations were generally considered clear and understandable. However, some participants indicated that they struggled to fully grasp the nuances of their surgical treatment, which resulted in an inability to articulate details, such as margins.

> "*[The physician] explained things well, telling me clearly that it looked like melanoma. It didn't worry me more than that. It's removable, so no apprehension."* P06

> "*It reassured me. When things are clearly stated and explained, there's no problem making a decision."* P10

This highlights the participants' appreciation for being well informed and involved in their own healthcare decisions.

Being aware of cancer risk

A recurring aspect of the discussions was the clinical diagnosis given to the patient during preoperative consultation. Five participants spontaneously associated their suspicious lesion

with a personal or family history of melanoma or other cancer, telling a story about a relative or friend. Perceiving themselves as being at increased risk, these participants leaned toward more extensive surgical intervention. Before the consultation, some participants suspected the diagnosis and already searched on the Internet or asked relatives for health information about melanoma.

> *"Well, I needed some reassurance given my dad's history, and to say to myself, "Well, I'd rather take that [large excision] to comfort myself because, you never know."* P14

> *"I suspected it [melanoma]. I suspected. I'd already even looked it up on the internet."* P11

These comments show the participants' perception of surgery as a protective measure for recovery while minimizing the chances of recurrence or spread.

Personal factors considered in treatment decisions

Patients cited a variety of reasons when deciding to have one- or two-step surgery.

Personal convenience of one-step surgery

An important reason favoring one-step surgery by all respondents was the aversion to surgery and the desire to minimize the number of surgical procedures given the convenience of only one procedure with a faster recovery. They also noted the benefits of fewer hospital visits, which saves work and travel time, especially for patients who live far from the hospital. One patient also expressed a fear of needles.

> *"What's more, by only doing it once, I had no apprehensions or preconceived ideas about how it would go. Whereas if you go back a second time, you know what happened to you, and you don't want to do it again."* P05

> *"I live far away, so it was also a choice based on distance."* P08

"It was really the phobia of getting a shot." P09

Participants appreciated having a choice and being able to decide based on their personal needs.

> *"I thought it was good ... to have the choice between two solutions, which seemed to be equally safe, but adapting it to my personal needs."* P03, chose one-step.

These data emphasize the importance of taking into consideration personal convenience and minimizing disruptions in patients' daily lives.

Choosing two-step surgery: following the guidelines

Only one participant in group A (P16) chose the two-step strategy for a suspicious lesion on his arm because he preferred the "safety" of a definite diagnosis and the possibility of an alternative benign diagnosis before proceeding further.

> "*What I really appreciated was being given the choice between 2 solutions. (...) I listened, and I chose safety, or caution, or safety, it's all the same."* P16

This patient valued following the guidelines and adhering to established medical procedures. He preferred a careful approach to his medical condition, not taking unnecessary risks of a wrong clinical diagnosis and thus excessive surgery.

Making choices, bearing responsibility

This category implies different levels of patient involvement in the decision-making process.

Different degrees of involvement

Most patients were satisfied that a healthcare professional took into account their opinion and let them decide which surgical strategy they preferred. They felt considered and respected. Participants' autonomy in decision-making was also influenced by their lack of medical knowledge. Some patients did not feel confident deciding and asked the healthcare provider to

guide them, highlighting an interest in shared decision-making. Many patients decided by themselves after hearing the medical explanations, occasionally with the support of a family member present during the consultation. Most patients appreciated having the autonomy to make decisions.

> *"I made the decision all by myself."* P08

Different views on responsibility

Patients were willing to take or at least share responsibility for the final decision and not blame their healthcare provider. One said that the patient should be involved in decisions whenever possible, as a right and duty granted to the patient. In contrast, one patient stated that she came to the hospital to be guided but was also satisfied with having the choice.

> *"But I think that hospitals are obliged to leave some responsibility to the patient, insofar as the patient can."* P16

> *"It's true that having a choice changes things when sometimes we come to be guided. And in the end, it was good to have it too."* P15

Need to value the trade-offs

When a diagnosis of melanoma was clinically uncertain, patients still accepted the risk of an unnecessary large excision for a benign lesion. They would rather have wide local excision (WLE) of the lesion than undergo an additional surgical procedure if it was melanoma.

> *"I was able to choose to have a slightly larger scar right away to avoid a second procedure."* P03

> "*Well, at least we know everything's off. So, it's all gone."* P06

Those who had a lesion on the body said that this decision was not the case for tumors located in visible anatomic regions such as the face because of the aesthetic impact of a scar.

> *"Beyond the face, of course, but even on the hands, on … well, on a more visible part of the body, I would have made a different decision."* P08

> *"And as the mole was on my back, I didn't mind having a slightly larger scar. It's true that if it had been on another part of my body, ... I might not have made that choice."* P01

Two participants (P08, P12) with facial melanoma did not regret choosing one-step surgery. P08 had a partial biopsy that confirmed the diagnosis and gave her the option of 5- or 10-mm margins because the sonography thickness revealed an intra-epidermal lesion. She chose the smaller margins because she was concerned about the potential width of the scar. P12 did not have a prior biopsy, but he easily decided on WLE from the outset given the sonometric thickness of 0.4 mm.

US reassurance

Reducing anxiety

Patients receive the news of the diagnosis during the same consultation as the US examination and surgical explanations. From clinical diagnosis until the histology results, participants may feel worried and anxious.

> "*And then, yes, we're always afraid of whether it's cancerous or what. Because it's a long wait, we have to wait 3 weeks to find out if the tumor is cancerous or not."* P13

> *"The fact that you measured it and saw that it wasn't too thick reassured me."* P15

Participants found the US examination reassuring because it gave them immediately information about the tumor's depth and thus its prognosis without having to wait for the

histology report. They expressed being relieved that the tumor was not too thick and that the results were explained by the physician. This finding suggests that US examination can be a valuable tool for reducing anxiety.

Reducing the delay of being treated

Most participants felt rushed into having the melanoma removed with WLE for complete treatment. They often reported that US examination allowed the physicians to see in-depth, which justified one-step surgery. They may have been anxious about their diagnosis and wanted to get the surgery over with as soon as possible. They may have also been concerned about the risk of waiting, such as the possibility that the cancer could spread.

> *"But in one-step, you get rid of it."* P06
>
> *"One-step surgery is better. It's over, it's done. That's why."* P09

These comments underline patients' awareness of the benefits of one-step surgery and a desire for the cancer to be treated as quickly as possible.

Patient satisfaction

Taking results as a judge for a right or wrong decision

This theme explored participants' reactions to histology analysis after surgery. The histology analysis seemed to influence patients' perception of their surgical decision. Six of the patients had an excessive excision from 5 to 10 mm, and one (P02) expressed disappointment because of an excessive margin of 5 mm. One patient (P12) underwent one- and two-step surgery for two different lesions, but he would have preferred one-step surgery for both and felt disappointed that we did not understand his preference during the preoperative consultation.

> *"Oh dear, we've taken everything off! Oh well, that's all right...."* P02

"Well, the diagnosis was right in the end; it was the right solution, so I think we made the right choice." P08

"What counts is the result, … without having to intervene a second time." P10

Many patients were satisfied with their decision and that they did not have to undergo an additional intervention, regardless of the final diagnosis, including a benign lesion. Of the 4 patients in group A with a personal or family history of melanoma, 3 ultimately had a diagnosis of nevi. P03 had a history of melanoma and an emotionally painful memory of his first surgical experience. He was satisfied to be able to manage his emotions by choosing the surgical strategy. P07 and P14 opted for WLE because the suspected lesion was in a less visible region (trunk, arm). P14 also had a family history of melanoma in her father and grandfather, and she expressed a fear of the same diagnosis.

Improving communication to achieve satisfaction

Participants were generally satisfied with surgical outcomes, particularly the appearance of the scar, but some were surprised at the width of the scar. However, they would choose the same procedure again. Two patients (P05, P10) with plantar melanoma did not expect a long recovery with limited movement. They felt that the dermatologist did not adequately prepare them for this, which affected their emotional and physical outcomes.

"*When I first saw this crater, I was impressed!"* P10

"*I didn't expect it to take this long at all, and no one can tell me .... So,it's already been almost 2 months, and I can only walk on tiptoe and I'm in a wheelchair..., so nobody said it would take this long."* P05

Patients felt that the dermatologist should have given them more information about what to expect after surgery. The importance of informing patients about postoperative outcomes must be emphasized.

Group B perceptions of one-step surgery

Participants who were not given the opportunity to discuss the one-step surgery option before undergoing WLE were asked what they would do if given the choice between the one-step and two-step procedure. All 5 of these patients replied that they would probably have preferred a one-step strategy because they did not see much difference between the 2 strategies. They expressed a preference for not having to come back for additional surgical interventions.

"*Well, I don't see the point of doing it twice when you can do it all at once."* P20

They said that they would trust the physician in either case. However, they acknowledged that it was a difficult question to answer because they had already undergone surgery. Nevertheless, satisfaction with the two-step procedure and overall experience was also noted.

DISCUSSION

To the best of our knowledge, this is the first qualitative study to explore patients' perceptions and experiences of the decision-making process for one-step surgery for primary cutaneous melanoma. The findings provide insights into the various factors affecting patients' understanding, preferences, emotions, and satisfaction as they go through the diagnosis, decision-making, and postoperative outcomes. Patients expressed an overall positive experience. Twenty of the 21 participants expressed a clear preference for one-step surgery, citing a personal aversion to surgery as the main reason for their preference.

Participants emphasized the critical role of clear and understandable medical explanations of the diagnosis and surgical treatment options in guiding their decision. However, some patients did not fully understand the one-step surgical approach, which underscores the importance of effective communication between healthcare professionals and patients. This finding is consistent with existing research that underlines the importance of patient-centered communication and shared decision-making in promoting informed choices (24). Some participants had a high awareness of their skin cancer risk due to a personal or family history of cancer. These patients were more likely to show interest in one-step surgery rather than standard two-step surgery probably because of their fear of cancer and desire for rapid treatment. At-risk families have been identified as ambassadors who can provide information on melanoma prevention and detection to others (25).

Regarding patient involvement, few patients adopted a traditional role, relying on healthcare professionals to make treatment decisions on their behalf. However, this approach may inadvertently overlook patient values and preferences, thus resulting in a disconnect between the treatment plan and the patient's wishes in that the physician may misunderstand (26). Most patients were satisfied with deciding for themselves in a shared decision-making process. This observation aligns with melanoma patients' wish to be seen as capable and resourceful individuals who can manage information during the diagnostic process and access to care (27). Participants' choices were influenced by several factors such as the perceived convenience of the procedure, medical reassurance, and the desire to avoid additional surgery. The decision-making differed depending on the tumor location because the esthetic outcome was a major concern that could affect patients' social life. Patients reported that they were more likely to undergo two-step surgery for melanoma located on the face to avoid excessive margins. In fact, patients are more satisfied if the scar is small and located away from the center of the face (28).

The impact of anxiety and uncertainty of a melanoma diagnosis and the decision-making process cannot be underestimated. Patients often experienced these feelings, which were alleviated to some extent by the reassurance provided by the dermatologist with the US examination. These findings underscore the need for better psychological support for patients within their care and the importance of integrating psychology into cancer care to address patients' emotional challenges (29). Trust in the healthcare professional could have influenced patients' choice. In fact, several patients mentioned the feeling of trust if they wanted to undergo treatment. Because of limited medical understanding, patients often follow physicians' instructions. Therefore, patients must be provided with clear, honest and truthful information regarding the diagnosis and surgical treatment, recognizing that they may be going through an overwhelming experience when receiving the diagnosis during preoperative consultation (30,31). Beyond counseling, time to think and educational material would help patients learn about their diagnosis and treatment options (32).

Patients' satisfaction with the surgical outcomes was tied to their overall care experience, including postoperative support and information about potential postoperative outcomes. Another qualitative study noted the discrepancy between patients' expectations of a scar versus their actual postoperative appearance (33), which suggests that the healthcare professional should focus on not only the surgical procedure itself but also the holistic care of the patient.

Strengths and limitations

The strength of this study is the use of qualitative methods, which allowed for an in-depth assessment of patient perceptions of this unexplored topic. Using semi-structured interviews soon after surgery reduced recall bias. Our study design conformed to 29 of the 32 criteria of the COREQ checklist.

The first limitation is inherent to the qualitative nature of the study in that we interviewed only a small number of patients from only one academic hospital. Second, HFUS is not widely available in all hospitals and requires experienced operators. Therefore, one-step surgery may not be adopted in daily practice in France. However, 13- to 18-MHz US probes are more commonly used in radiological clinical practice and could be used to measure cutaneous melanoma thickness but with lower resolution than HFUS (4,12,34,35). The risks of overestimating Breslow thickness and of false diagnosis of malignancy are the main disadvantages of the one step-surgery. Third, because almost all patients did not choose the two-step surgery, we asked patients who underwent WLE in two-step surgery about what they would think of US examination and one-step surgery. Fourth, the researcher LM may have induced a bias by his experience in the use of HFUS and one-step surgery and could have affected patients' responses during the preoperative consultation. However, he was also the most experienced to explain the procedure. Finally, almost all histology analyses showed < 1 mm Breslow thickness, which resulted in 10-mm margins and could have been more acceptable to patients than a maximum of 20-mm margins. Also, participants did not check the interview transcripts, which would have supported the validity of the findings.

Clinical implications

The clearest message to emerge from these interviews is the overall satisfaction with one-step surgery, explained by a perception of a pragmatic and fast surgical strategy guided by HFUS, a non-invasive examination, for melanoma. Clear and comprehensible delivery of information can empower patients to make informed decisions that align with their preferences and values to improve their quality of care.

Further research is needed on several aspects. For example, a study on the same topic could investigate perceptions of healthcare professionals (dermatologists, pathologists, surgeons) about one-step surgery. A decision support tool could facilitate both physicians and

patients in this decision making, similar to the validated patient decision aid for treating lentigo maligna of the head and neck (36). Finally, better understanding patients' preferences may reduce the cost of public healthcare given the reduced implication of histology analysis, surgeon's time, travel, and medical leave. Moreover, medico-economic advantages could be further studied.

Conclusions

In conclusion, one-step surgery should be proposed to patients after they are given adequate information. The study emphasizes the importance of patient-centered care associated with effective patient–physician communication providing informed choices. These insights can guide improved preoperative consultations and enhance shared decision-making between healthcare professionals and patients regarding melanoma treatment strategies. Further research is needed to understand healthcare professionals' perceptions about one-step surgery and to develop decision support tools for optimizing decision-making in melanoma treatment.

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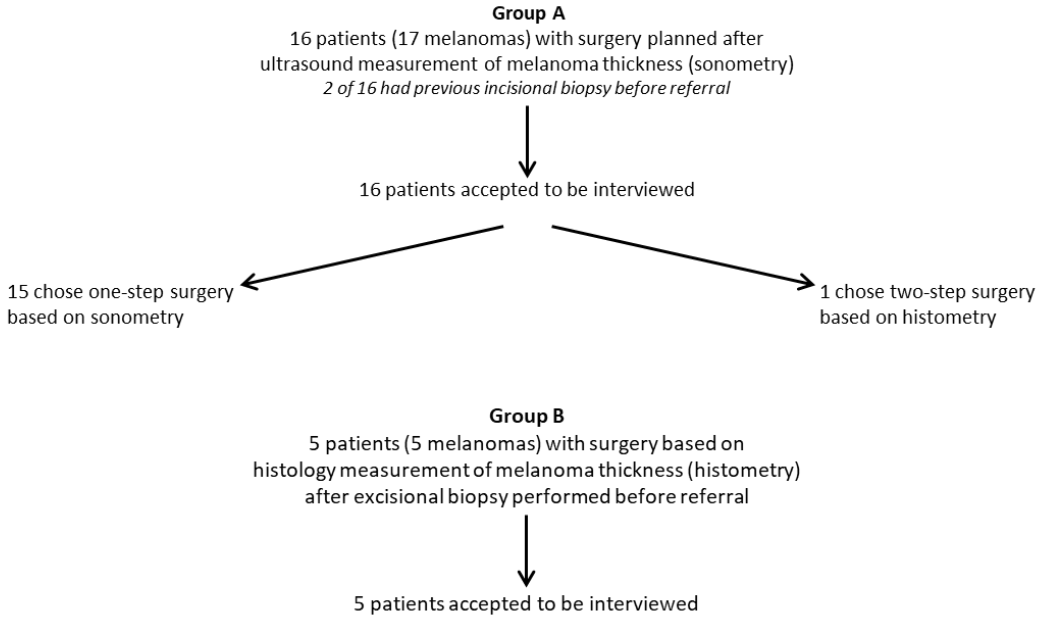
FIGURE ET TABLEAU

Figure 1. Flowchart diagram of participants in the study



Patient (P) number	Sex	Age (years)	Location	Pathology*	Partial skin biopsy	Sonometric thickness (mm)	Breslow index (mm)	Surgical margins (mm)	Excessive margins (mm)	One-step or two-step surgery**	Interview time from last surgery (days)	Education level***
Group A: sonometry before surgery												
P01	F	52	Trunk	SSM	No	0.5	0	10	5	1	30	UD
P02	F	49	Trunk	SSM	No	0.75	0	10	5	1	30	PSC
P03	M	31	Lower limb	SSM	No	0.6	0.6	10	No	1	27	UD
P04	M	49	Lower limb	Nevi	No	0.3	n/a	5	5	1	33	UD
P05	F	81	Sole	SSM	No	2	1.8	20	No	1	81	PSC
P06	F	43	Lower limb	SSM	No	0.3	0,6	10	No	1	211	UD
P07	M	32	Upper limb	Nevi	No	0.2	n/a	10	10	1	22	UD
P08	F	51	Face	LM	Yes	0	0	5	No	1	94	UD
P09	M	68	Trunk	SSM	No	0.5	0.65	10	No	1	18	SS
P10	F	73	Sole	ALM	Yes	0	0	10	5	1	27	UD
P11	F	55	Upper limb	SSM	No	2.25	2	20	No	1	21	PSC
P12	M	69	Trunk	SSM	No	0.4	0.25	10	No	1	16	SS
			Trunk	SSM	No	0.4	0.5	10	n/a	2	16	
P13	M	67	Face	LM	No	0.4	0	10	No	1	78	PSC
P14	F	35	Trunk	Nevi	No	0.2	n/a	10	10	1	13	PSC
P15	F	33	Lower limb	SSM	No	0.4	0.75	10	No	1	15	UD
P16	M	32	Upper limb	SSM	No	0.3	0.3	10	n/a	2	6	SS
Group B: histometry before surgery												
P17	M	66	Trunk	SSM	No	n/a	0	5	n/a	2	7	UD
P18	M	75	Upper limb	SSM	No	n/a	0.2	10	n/a	2	1	HSD
P19	F	34	Upper limb	SSM	No	n/a	0	5	n/a	2	47	PSC
P20	F	75	Upper limb	SSM	No	n/a	2.6	20	n/a	2	21	PSC
P21	F	59	Lower limb	SSM	No	n/a	0.7	10	n/a	2	26	HSD

Table 1. Characteristics of patients

F: female; M: male; n/a: not applicable
*SSM: superficial spreading melanoma; LM: lentigo malignant; ALM: acral lentiginous melanoma.
**1: one-step surgery; 2: two-step surgery
***SS: Secondary school; HSD: high school diploma; PSC: professional study certificate; UD: university degree

ANNEXES

Annexe 1 Guide d'entretien

Appendix S1: Interview guide

Hello, thank you for taking part to this research project. We are interviewing patients with cutaneous melanoma, and we would like to know your views on your experience to the use of some questions. The interview should take approximately 30 minutes. With your permission, it will be audio-recorded but any identifying information about yourself during our discussion will be removed from the interview transcripts. You are free to withdraw from the study at any time, during or after the interview.
Note: these questions are meant to be used if the topics do not naturally arise in conversation. The order of questions can change depending on how the participant answers the questions.

Questions for group A

1-Tell me about your preoperative consultation.

Prompts:
What did the dermatologist explain to you?
What did you understand about your diagnosis? your treatment options?

2-Why did you decide to have a [one-step] or [two-step] surgery?

Prompts:
What were the advantages and disadvantages of taking this option?
What factors did you consider in your decision?
How did you feel about following or not recommendations guidelines?

3-How did you experience the choice between 2 options?

Prompts:
Did you feel you had an option to choose?
What was your reaction?
How did you feel about being involved in the decision-making process?

4- What do you think about the surgery guided by the skin ultrasound?

Prompts:
What did you understand about the purpose of the examination?
What do you think about the discrepancy in thickness between the ultrasound and the histological result?

5-Tell me about the results.

Prompts:
How would you react if there was a margin error that resulted in a larger scar?
Would you have made the same choice if the lesion was on your face? on another part of your body?

6-Do you have any suggestions or comments to make regarding the use of pre-operative ultrasound? the surgical management of melanoma? the preoperative consultation?
Would you like to talk about other topics before we end?

Questions for group B

After explaining the principle of one-step surgery guided by HFUS to the patients who underwent wide local excision in a two-step surgery, we asked questions below.

1-What would you choose if you were given the choice between one-step or the standard procedure? Why?

Prompts:
What are the advantages and disadvantages of each option?
What factors would you consider when making this decision?

2- How would you feel about this choice to make?

3-Do you have any comments to make before we end?

Demographic questions for both groups:

- Sex
- Age
- Education level

<u>Annexe 2</u> Avis du groupe éthique

GROUPE ETHIQUE D'AIDE A LA RECHERCHE CLINIQUE POUR LES PROTOCOLES DE RECHERCHE NON SOUMIS AU COMITE DE PROTECTION DES PERSONNES
ETHICS COMMITTEE IN HUMAN RESEARCH

AVIS

Responsable de la recherche : Mme LIM et Pr MACHET
Titre du projet de recherche : Mélanome cutané : préférences des patients pour une opération d'emblée en 1 seul temps après mesure échographique de l'épaisseur tumorale.

N° du projet : 2022 027

Le groupe éthique d'aide à la recherche clinique donne un avis

X **FAVORABLE**

☐ **DÉFAVORABLE**

☐ **SURSIS A STATUER**

☐ **DÉCLARATION D'INCOMPÉTENCE**

au projet de recherche n° 2022 027

A Tours, le 05/01/2023

Dr Béatrice Birmelé
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Annexe 3 Grille COREQ 32

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007 Dec;19(6):349–57

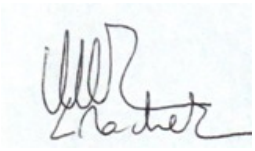
No. Item	Guide questions/description	Responses
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Laurent Machet (LM) and Margueritte Lim (ML)
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	LM: MD, PhD ML: MD
3. Occupation	What was their occupation at the time of the study?	Dermatology senior and resident
4. Gender	Was the researcher male or female?	LM: male ML: female
5. Experience and training	What experience or training did the researcher have?	New to qualitative research, supervised by a general practitioner experienced in qualitative research
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	No
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants were briefed on the purpose of the study. Participants received a participant information documentation.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	10+ years' experience in skin ultrasonography for the measurement of melanoma thickness.
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Qualitative research, general inductive approach
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposive
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face
12. Sample size	How many participants were in the study?	21

13. Non-participation	How many people refused to participate or dropped out? Reasons?	None
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Tours hospital, 1 at patient's home
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Yes, sometimes an accompanying person was present during consultation
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Cf. Table 1
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes (Appendix 1), yes
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Audio recording
20. Field notes	Were field notes made during and/or after the interview or focus group?	During the interview
21. Duration	What was the duration of the interviews or focus group?	Mean duration 21 min
22. Data saturation	Was data saturation discussed?	Yes
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	2 (LM and ML)
25. Description of the coding tree	Did authors provide a description of the coding tree?	No
26. Derivation of themes	Were themes identified in advance or derived from the data?	Themes were derived from the data
27. Software	What software, if applicable, was used to manage the data?	Microsoft Word and Excel
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Yes
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

CONCLUSION GENERALE

Cette étude qualitative est la première à explorer les perceptions des patients atteints de mélanome cutané sur la chirurgie en un temps opératoire. Nos résultats suggèrent qu'une telle stratégie pourrait être proposée et choisie par les patients ayant une lésion suspecte de mélanome. La chirurgie en un temps est préférée pour plusieurs raisons : une meilleure qualité de vie car évite une deuxième intervention chirurgicale ; un sentiment de réassurance par le biais de la mesure de l'épaisseur maximale échographique, permettant au patient de mieux comprendre son pronostic et une implication du patient dans le processus décisionnel lui permettant de prendre en compte ses préférences. Les patients atteints de mélanome cutané devraient donc être informés des 2 options chirurgicales possibles (1 ou 2 temps opératoires) lorsque l'utilisation de l'échographie cutanée haute résolution est disponible. L'amélioration de la consultation préopératoire passe par la délivrance d'informations claires et complètes sur le diagnostic, les options chirurgicales et une meilleure communication sur les suites post-opératoires dans le but d'aider à la prise de décision éclairée concernant le choix du traitement chirurgical du mélanome. La chirurgie en un temps opératoire guidée par l'échographie cutanée est une approche prometteuse qui pourrait améliorer la qualité des soins et de vie des patients.

Vu, le Directeur de Thèse



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LIM Margueritte

53 pages – 1 tableau – 4 figures – 3 annexes

Résumé : Introduction. L'échographie cutanée haute résolution (> 20 MHz), permet la mesure préopératoire de l'épaisseur du mélanome cutané, bien corrélée à l'épaisseur histologique (indice de Breslow). La chirurgie en 1 temps opératoire guidée par l'échographie cutanée est une nouvelle approche combinant le diagnostic et le traitement du mélanome en une seule intervention chirurgicale d'emblée avec des marges adéquates. Les avantages potentiels d'une telle stratégie pour les patients restent à explorer. **Objectif.** Explorer les perceptions des patients sur la proposition d'une chirurgie en 1 ou en 2 temps opératoires pour traiter leur mélanome cutané primitif. **Méthodes.** Etude qualitative par entretiens individuels semi-directifs auprès de 2 groupes. Les patients du groupe A ont reçu la proposition d'une chirurgie en 1 ou 2 temps, après la pratique d'une échographie cutanée préopératoire. Les patients du groupe B ont été opérés en 2 temps (exérèse sans marge suivie d'une reprise chirurgicale), sans proposition préalable d'une chirurgie en 1 temps. Les entretiens ont été audio-enregistrés et analysés selon une approche inductive générale. **Résultats.** Vingt-et-un patients, 16 dans le groupe A et 5 dans le groupe B, ont été interrogés. Les patients du groupe A exprimaient une nette préférence pour une chirurgie en 1 temps opératoire. Ils appréciaient être associés à la décision chirurgicale et étaient rassurés par la mesure de l'épaisseur maximale échographique, malgré le diagnostic de mélanome. La communication des médecins sur les suites opératoires doit être améliorée. Les patients du groupe B sont également satisfaits de leur prise en charge, bien qu'ils auraient préféré une chirurgie en 1 seul temps si on leur en avait fait la proposition avant la première exérèse. **Conclusion.** La chirurgie en un temps peut être proposée aux patients après informations claires et complètes sur le diagnostic, le traitement et les suites opératoires lors de la consultation préopératoire. Mettre le patient au centre du processus décisionnel améliorerait la qualité des soins.

Mots clés : mélanome, marges d'exérèse, échographie cutanée, décision partagée, décision de traitement, recherche qualitative

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