

Practices, beliefs, and attitudes of clinicians in prescribing direct oral anticoagulants for obese adults with atrial fibrillation

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Abstract

Background: Atrial fibrillation (AF) and obesity affect over 60 and 650 million people, respectively.

Aim: To explore clinician practices, beliefs, and attitudes towards the use of direct oral anticoagulants (DOACs) in obese individuals with AF.

Methods: An exploratory qualitative interview study of clinicians, with expertise in DOAC use in individuals with AF. Data was analysed in NVIVO using thematic analysis.

Results: Fifteen clinicians including cardiologists (n=5), hospital pharmacists (n=5), general practitioners (n=2), a haematologist, a neurologist and a clinical pharmacologist participated. Interviews lasted for an average of 31 ± 9 minutes. Key themes revealed were:

(1) *Health system factors in decision-making:* Disparities between rural and metropolitan geographic areas, with regards to access, availability of health services, and time limitations for in-patient decision making, were described.

(2) *Condition related factors in decision-making:* Clinicians questioned the significance of obesity as part of decision-making due to the practical limitations of dose modification, and the rarity of the extreme obese cohort.

(3) *Decision-making in the context of uncertainty:* Clinicians reported limited availability, reliability and awareness of primary evidence including limited guidance from clinical guidelines for DOAC use in obesity.

Conclusion: The interplay between obesity and AF, in the context of a challenging healthcare environment, impacts DOAC prescription decision-making. This study highlights limitations in availability, reliability, and awareness of evidence. The intrinsic complexity of the obese cohort coupled with limited guidance from clinical practice guidelines, equates to an urgent need for contemporary research to improve the quality of evidence to guide informed shared decision-making.

Impacts On Practice

- There is disagreement on the use of DOACs in obese individuals with AF
- Beliefs & attitudes of a clinician may affect their decision-making process
- Clinicians are faced with dealing with intrinsic complexities of obesity with limited guidance
- Current limitations highlight the need for improvement in the quality & availability of evidence to help guide clinicians

Introduction

Atrial fibrillation (AF) and obesity are two of the most prevalent conditions in the world, affecting 60 and 650 million people globally, respectively [1, 2]. It is estimated that obesity increases the risk of developing AF by up to 50% and almost one in five cases of AF are attributed to obesity, to the extent that there is a 4–5% increase in AF risk for each incremental increase in body mass index (BMI) [3–6].

Obesity increases unplanned, cardiovascular-related, and all-cause hospital admissions in patients with AF [7]. Studies highlight the complex interplay of pathophysiological mechanisms with changes in hemodynamic, autonomic, and inflammatory responses and structural remodelling [8–14] influencing the pharmacokinetics of medications used in AF management [15].

There is disagreement in pharmacokinetic reports of direct oral anticoagulants (DOACs) peak and trough plasma concentrations when comparing normal and obese individuals [16–19]. This disagreement pervades opinion regarding the clinical effect of obesity in the context of DOACs, given the lack of long-term outcome data and variability in prescribing [20, 21]. Clinician perceptions of uncertainty, the need for individualised decision-making, and attitudes toward delegation of responsibility may be factors in reluctance to treat with anticoagulants [22].

Clinicians formulate distinct intellectual responses to available scientific evidence, the prospect of emerging evidence, monitoring mechanisms and safety concerns, especially with regards to the potential to cause harm and accountability for that harm [23]. Inherent bias in the context of no data to support viewpoints, influences racial and socioeconomic prejudice and prescribing [23, 24]. Although views on decision making and prescribing anticoagulants in patients with AF have been explored in several studies [22, 23, 25–33], there is very limited research investigating clinicians' perspectives of the effect of obesity on anticoagulants in patients with AF.

Aim

The aim of this study was to explore clinician practices, beliefs, and attitudes towards pharmacological management in obese patients with AF.

Ethics Approval

The study was approved by Western Sydney Local Health District (REF: 2020/ETH03065; 06/01/2021) and Western Sydney University (REF: RH14416; 12/07/2021) Human Research Ethics Committee.

Method

Design:

Semi-structured interviews with open-ended questions were conducted to explore multidisciplinary clinician's perceptions (Supplemental Table 1: Interview Guide). This study follows the Standards for Reporting Qualitative Research (SRQR) [34].

Setting & Sample

Clinicians from across Australia with expertise in the use of DOACs in patients with AF, from either a medical, pharmacy or nursing background, were invited to participate via a combination of purposive and snowball sampling techniques.

Procedure

Invitations for interview sent via email included an outline of the proposed research. Clinicians who agreed were asked to sign and return the consent form, and a mutual time was confirmed to conduct one-on-one interviews via video conference. Interviews were recorded, and hand-written field notes were taken to supplement verbatim interview transcripts as interviews progressed. Clinicians could withdraw from the study at any point.

Data Analysis

Concurrent interviews and data analysis enabled efficient identification of the point of data saturation where no new themes emerged from ongoing interviews. Verbatim transcriptions were checked for validity against the audio and manually recorded data. Transcriptions were uploaded and managed using NVIVO software (QSR International, 2020). Thematic analysis was conducted in accordance with the Braun and Clarke (2015) framework [35]. Each transcript was read and coded independently by two authors (FS, CF) to identify initial themes subsequently confirmed by a third member of the team (RW).

Results

A total of 16 clinicians; cardiologists (n = 5), pharmacists (n = 5), general practitioners (n = 2), a haematologist, neurologist, clinical pharmacologist, and a clinical nurse consultant (CNC), agreed to participate but the CNC withdrew on the premise of a lack of experience focused specifically on the intersection of obesity and AF. Nine (60%) were male and experience ranged from relatively junior (3 years of practice) to senior clinicians working in their specialty for up to 39 years. Interviews lasted for 31 ± 9 minutes, and three key themes were identified: 1) health system factors in decision-making, 2) condition related factors in decision-making, and 3) decision-making in the context of uncertainty, discussed in detail below.

Health system factors in decision making

Clinicians in rural general practice settings highlighted disparities within the healthcare system as barriers to decision-making. These included access and availability of health services, and longer waiting times for specialist services in rural/regional areas when compared to metropolitan areas (i.e., Sydney or Melbourne), influencing delays in the initiation of anticoagulation.

“Because I do get the impression from people who are right in the middle of Melbourne and Sydney, that they just tend to refer a lot of people. And of course, you can't afford to be like that in a region like ours, or if you're more rurally based. I mean, you'd be waiting quite a long time to get access and care for the patients” - General Practitioner 01

“So, you know, you, you will say that there will be referrals, for patients to address that, but even still, obesity clinics and services and the clinicians that are specialised in this space, are still far and few between and the waiting lists to get into those places are I'm told are quite long” - Pharmacist 01

Clinicians from hospital settings questioned the need for urgency in treatment decisions when prescribing DOACs in the context of obesity. Some acknowledged the importance of taking obesity into consideration when decision-making, but their primary concern was related to the significance of incorporating obesity into decision-making during time constrained, acute hospitalisations. Time was a barrier to effective decision-making and clinicians reported frequently having to overlook potentially influential factors because of the inability to obtain immediate results.

“.. . you know, the obesity is important, and everyone will acknowledge that, but at the end of the day, they're managing what they have in front of them that is distressing symptomatically and clinically to the patient, and it's impacting on them functionally, and that they're easier things to deal with cause you can initiate therapy for that. You know, pharmacologically, non-pharmacologically. But dealing with the obesity, that's a whole other thing, and that can't be addressed, to any practical means, like there's nothing that you can practically do in an, hospital admission, that is gonna have a significant impact on that patient's obesity status. You know, that, that's still a long process...relative to what you can do fairly quickly. So, it, it's important clinically, but in terms of management in a hospital where you have, you know, a relatively short period of time, you don't have months, you know, to, to kind of reverse, obesity in somebody that's really suffering. Yeah. You, you, you're limited to what you can do” – Pharmacist 01

Influence of obesity in decision-making

Clinicians emphasised the rarity of the obese AF patient population as a factor that leads them to question the clinical significance of obesity as part of their decision-making. Clinicians often referred to obese patients as a “rare cohort”, with most expressing doubts related to dealing with obese AF patients.

“I have not, in my practice, changed the dosage of those drugs for morbid obesity, but I don't treat anyone who's obese, so it hasn't actually come to in my own practice” – Cardiologist 01

“I don't know very many patients with AF who are the morbidly obese category”- General Practitioner 02

"... cause they are a rarer group, even though obesity is on the rise, but the morbidly obese patient is, you know, a relatively smaller part of the population" – Pharmacist 01

Some clinicians acknowledged the importance of taking into consideration the associated complexities of care for obese patients. This was generally discussed in terms of the multiple co-morbidities that exist in obese individuals, often referred to as a *"special population"* or *"cohort own on their own"*. However, this also led to some clinicians questioning the importance of obesity in the overall management strategy, secondary to limitations on the practical implementation of dose adjustments and services provided.

"I wouldn't worry about it. So, I worry much more about the renal side of things because the renal side of things can change so quickly, and it's so responsive to things like diuretics, fluid status, nephrotoxic, ACE inhibitors, [inaudible], the integral flows and medication that's coming on the market now for heart failure. There are so many more things that would worry me about the kidney function that could then impact upon the NOAC dosing, that that is the very much front and centre of my mind. But when I'm thinking about body weight in the dosing of a NOAC, I think about it at one point of time, which is at the time when the initial prescription is made. At that point, I'll consult and then pretty well, after that, I'll just forget about it."- Clinical Pharmacologist

Decision-making in the context of uncertainty

Participants were concerned about the availability, reliability, and high level of uncertainty of evidence for DOAC use in obesity. They questioned the quality of obesity evidence due to limitations in clinical trial inclusion criteria, conflicting evidence, and variability in advice. The lack of direction from guidelines because of the unknowns in this aspect of practice were noted, often disliking the approaches taken as they felt 'left in the dark' and generally on their own to make decisions.

"Yeah, I'm aware of that as a guideline, and I really don't like it because it's not practical. That's where I think we need to address this, because 120 kilos is pretty easy to say. It's not that heavy. And there are a lot of patients around at that weight, and they're at really high risk, because they've got spaces, because they're, they don't move around very much. They have, lots of, of tissue pushing up against the blood vessels. They've got lots of injuries, they've got lots of medications on-board. There's lots of reasons for them to then have issues with thrombosis. And we're saying, "Ah, sorry, we just haven't done the studies." And so, you'll have to go on warfarin. And then there's the issues of the blood test. So, I actually think it's quite discriminatory, that we haven't addressed this more seriously than, other than saying, ah, we don't have the data w- we, we do it. So, I think either we go and get the data by just doing trials, or we get the data in other ways. So, there are, there are ways, epidemiological ways to look at safety. In this population, you can, you can get prescribing data from Medicare and figure out what their weights are from various other ways and means. We can look at, some population who are going gastric, who are doing gastric banding, and then give them, give them, NOACs postoperatively and see or preoperatively and see, we see, you've got a cohort there, and if it's ready, they're ready to go, you can test on them. It's not that difficult to do. And the fact that we haven't done it, I think is wrong" – Clinical Pharmacologist

Clinicians stated the presence of a lag period from evidence generation to implementation or awareness of the evidence in practice, impacted on decision-making.

".. . the guidelines are always a tricky thing and I always say, you know, just remember the guidelines are just a guide and, almost as soon as they're written, they're out of date"- Pharmacist 01

Treatment outcome appeared to be a primary concern for clinicians and the main factor taken into consideration when decision-making. Possibilities included the risk-benefit of anticoagulation, the clinical significance of obesity influencing DOAC effectiveness and known DOAC safety profiles. Concerns about bleeding risk with dose modification led to decision-making based on the first principal approach. This would vary depending on individual clinician belief regarding the quality of evidence, combined with past clinical and prescribing experience.

"Clinicians that have had a patient experience a negative effect will employ a more cautious approach, as opposed to some who hasn't experienced this" – Pharmacist 01

Whilst acknowledging the lack of evidence/data and limitations in predicting future outcomes, some clinicians believed that the *"absence of data, is not the absence of effect"*.

"I was saying that we don't have any randomized control data for NOACS against placebo or nothing. Okay? We do have a limited number of things that were, summarized by, in a meta-analysis and on which basis the recommendations for giving, oral coagulation for non-valvular AF have been made. In those studies, which are much smaller than the NOAC studies in general, as far as I'm aware, there was no, no mention or sort of segregation of people who were morbidly obese. So, in other words, we don't have data on morbidly obese people with Warfarin, but at least with Warfarin you are dealing with, trying to get people to a certain INR, not sort of give them a dose. With DOACs, we're not using a dose. I do not, I do not subscribe to the fact that the absence of data means the absence of effect, and in the absence of data, I have just used that and tried to reduce obesity as, as a matter of fact. So that's my management." - Cardiologist 01

Clinicians often stressed the importance of an integrated, multidisciplinary approach and shared decision-making to provide the optimal level of care for the patient. This included collaborating and relying on interprofessional expertise, acknowledging their respective professional scope of practice and ensuring continuity of care. Whilst accounting for preferences and past experiences of patients, considering current evidence and risk-benefit of being on a different agent, most often patients would trust the preference of the prescribing doctor.

"The... most of the patients I see... I generally not... I, I explain what... you know, the process that we are going through. They're, they're generally pretty comfortable with the decisions I make. I used to give them a whole lot of information about the... you know, various... various options. I... in the end,.. it became clear that that wasn't... didn't really impact very much on the decisions that were made. And, in the end they generally went with what I recommended anyway." – Cardiologist 02

“look I'd probably, I'd probably, if given ... these patients mostly in hospital, I'd probably consult the- the pharmacist, the ward pharmacist at a minimum. Get them to do that hard work and look up the dosing changes or which agent we should use, one preferred to the other. Ultimately make I sort of make a decision based on what evidence they've shown” – Neurologist

“so, the way I would approach it is, so I actually have a chat with a pharmacist, because they're always really good with giving advice. But I understand there's a busy, there's a, you can use rivaroxaban up to a certain weight, and I would choose to go down that line, if I could. And then my understanding is that, you have, you have warfarin's, like at the extremes of weight, warfarin is recommended. But warfarin is really difficult to, administer, if you can't test for it. And often, if someone's morbidly obese, you can't... Getting blood out of them is credibly difficult. And so, I would usually under those circumstances, consult. Either a, at any regulation special- specialist or hematology, that would be my threshold of saying, I really much prefer to use and NOAC” – Clinical Pharmacologist

Discussion

This exploration of the practices, beliefs, and attitudes of clinicians in relation to the use of DOACs in obese individuals with AF highlights the spectrum of views with regards to taking obesity into consideration as part of the clinician's decision-making process. While almost all clinicians acknowledged the negative impacts of obesity on AF, only a few considered obesity as a key component in their decision-making for several reasons. Challenges within the healthcare system, the complexity of patients' presenting conditions and the fact that decision-making takes place in the context of uncertainty were amplified by time limitations, and geographical discrepancies in access to specialist healthcare advice and services.

In acute care facilities where demand is high, the urgency of cases clinicians need to treat perpetually limits time. Referral to outpatient services (e.g., anticoagulation clinics, home medicine review), and follow-up appointments in primary care to ensure appropriate and adequate treatment are proposed solutions [36–38] but these findings support the notion that geographical access challenges in Australia are a longstanding issue, evidenced by poorer health outcomes in rural versus metropolitan regions [39]. Specialist referral rates are significantly lower in “very remote” compared to “major city” (22 versus 143 per 100,000 population) areas. Complicating this is the higher prevalence of obese individuals in rural regions (70%) compared to “major cities” (65%) that burdens clinicians in rural settings with limited resources [39]. Telehealth in rural areas improves options via timely advice for decision-making. Several studies demonstrated successful implementation, continuity of care, improved patient outcome and satisfaction, with telehealth programs for anticoagulation care during COVID-19 [40–43].

Decision-making in the context of uncertain and often conflicting evidence was a major theme highlighted by participants due to either a lack of awareness of the latest evidence, personal conviction regarding the quality and reliability of data from trials and other studies, non-specificity in guidelines, and recognition that even the most contemporary guidelines are rapidly outdated as evidenced by the

translational lag between evidence generation and implementation [44]. The introduction of “living guidelines” provide an option for timely, contemporary evidence for clinicians [45, 46] that could negate translational lag. The importance and benefit of interprofessional collaboration and shared expertise in decision-making was perceived to optimise patient care in this study. Dreijer et al., tested a multidisciplinary antithrombotic team that significantly improved adherence to anticoagulant guidelines amongst prescribing clinicians [47]. Shared decision-making allows patients to take part in the process by considering their values and preferences [48]. This ultimately improves patient satisfaction, trust and adherence to medications [49]. Complimentary mechanisms augment patient care, improving health outcomes [50].

Consistent with previous research, evidence uncertainty, shared decision-making, personal preferences, and safety concerns are not new issues for prescribing clinicians [22, 23, 29, 31–33]. This work reveals the additional level of complexity obesity adds to decision-making. Whether it is safe and efficacious, to initiate or change dosing and choice of anticoagulant according to weight is unknown and influenced by internal and external barriers that prevent obesity being considered in decision-making. The absence of definitive guidelines substantiates the need for timely robust research examining the effect of obesity on DOACs in the context of AF. Stratification in trials is an immediate remedy to ensure comparable numbers of participants from BMI categories.

Strengths & Limitations

The practices, beliefs, and attitudes of clinicians are under-investigated. The recruitment of diverse clinicians for standardised interviews provided rich substantive information to improve our understanding of key concerns for managing obese patients with AF. A key limitation is the limited transferability or generalisability of these themes, however there were no new themes emerging on conclusion of recruitment. Findings provide clinician instigated hypothesis generating ideas for future research.

Conclusion

A range of views and perceptions of barriers to the incorporation of obesity as part of the decision-making process in AF, were revealed in this study. Findings highlight the complexity of decision-making for clinicians, due to limitations in evidence, the intrinsic complexity of the obese cohort and the absence of robust practice guidelines. To generate more conclusive evidence on the use of DOACs in the context of obesity, future research must focus on testing effect according to categories of BMI and “living” guidelines must inform shared decision-making, crucial to stem the negative outcomes associated with endemic obesity and AF.

Declarations

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Conflicts of Interest

CF is a co-author of the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand: Australian Clinical Guidelines for the Diagnosis and Management of Atrial Fibrillation 2018. All other authors declare no conflict of interest.

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