**Title:** Perceptions of General Dental Practitioners in Northern Ireland on the clinical management of patients taking Direct Oral Anticoagulants (DOACs)

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**Conflict of Interest**

The authors have no conflict of interests to declare.

**Précis**

Most GDPs in Northern Ireland are aware of the SDCEP guidance on management of patients taking anticoagulant or antiplatelets, but require additional training and support to prevent inappropriate referrals.

**Abstract**

*Statement of the problem:*

Despite guidance advocating the management of patients taking Direct Oral Anticoagulants in primary dental care settings, evidence from clinical audit in Northern Ireland suggested that a high proportion of patients were being referred to secondary and tertiary care settings for dental procedures with a bleeding risk.

*Purpose of the study*

The aim of this study was to evaluate the perceptions of General Dental Practitioners working in the Health Service in Northern Ireland on the clinical management of patients taking DOACs in primary dental care.

*Materials and Methods*

A questionnaire was distributed to the 1167 registered GDPs in Northern Ireland, assessing perceptions of the clinical management of DOAC patients in primary dental care. The data obtained was analysed using SPSS® statistical software. Qualitative data underwent thematic analysis.

*Results*

344 questionnaires were analysed. 83% (285) of responding GDPs were aware of the SDCEP guidelines. 98% (337) believed DOAC patients could potentially be managed in primary care but that additional training was required. 80% (275) of GDPs had referred DOAC patients to secondary care. Procedures presenting a low risk of postoperative bleeding complications accounted for 12% (41) of referrals.

*Conclusions*

A lack of GDP confidence and experience in the management of DOAC patients are motivating factors in referral to secondary care settings for treatment. 12% of the referrals analysed were potentially inappropriate, given the low risk of associated postoperative bleeding complications. Additional training and support for GDPs, as well as enhanced awareness of the SDCEP guidance is essential.

**Introduction**

Thromboembolic disease constitutes a leading cause of mortality and morbidity worldwide.1, 2 Anticoagulants are an essential tool in the management of patients with thromboembolic disease due to their role in preventing the blood hypercoagulability that plays a central role in thrombogenesis.3

A number of disadvantages associated with traditionally used oral anticoagulants such as Vitamin K antagonists (VKA) led to the development of Direct Oral Anticoagulants (DOACs), also known as Novel Oral Anticoagulants (NOACs), first introduced to the UK in 2008.2,4 DOACs are also referred to as target anticoagulants as they directly inactivate thrombin (FIIa) and Factor X (FXa). 5 DOACs offer several advantages over VKA; they are administered in standard doses, eliminate the need for dose titration and laboratory monitoring, have a rapid onset and offset of action as well as increased predictability and a lower incidence of major bleeding.5 There are currently four DOACs licensed for use in the UK: dabigatran, apixaban, edoxaban and rivaroxaban.6

Patients taking DOACs present an increased risk of bleeding during and following invasive dental procedures. The Scottish Dental Clinical Effectiveness Programme (SDCEP) published guidelines in 2015; ‘Management of Dental Patients Taking Anticoagulant or Antiplatelet Drugs7. This guidance includes advice on new generation anticoagulants and antiplatelets, including DOACs, for oral health professionals within primary dental care. The SDCEP guidelines advocate the management of patients taking DOACs in primary dental care, using procedure-specific bleeding risk to inform the need for alteration of the DOAC dose. These guidelines have been endorsed by the Department of Health (DoH) in Northern Ireland. Dental procedures unlikely to cause bleeding, those with a low risk of postoperative bleeding complications and those with a high risk of postoperative bleeding complications according to the SDCEP guidelines are clearly outlined in Table 17.

Insert Table 1

*Table 1: Post-operative bleeding risk classification for dental procedures as per SDCEP guidelines on ‘Management of Dental Patients Taking Anticoagulants or Antiplatelet Drugs’.*

Despite the recommendations of this guidance, evidence from clinical audit suggested that a high proportion of patients taking DOACs within Northern Ireland were being referred to secondary care settings for dental procedures with a bleeding risk. Previous evidence has suggested that a number of factors, including a lack of undergraduate oral surgery experience among recently qualified GDPs, as well as increasing numbers of patients retaining natural teeth, against a background of complex medical histories and polypharmacy, can contribute to such referral patterns.8 A survey of dentists in the Greater Manchester area found that 69% of respondents made a referral to secondary care services based on anticipated surgical difficulty, whilst 49% referred based on the complex nature of a patient’s medical history, including DOACs.9,10

The aim of this study was to evaluate the perception of GDPs in Northern Ireland on the management of patients taking DOACs in primary dental care, including their awareness of the relevant SDCEP guidance and the factors influencing referrals to secondary care settings. Ethical approval for the study was granted by the School of Biomedical Sciences Ethics Filter Committee at Ulster University.

**Materials and Methods**

*Inclusion and Exclusion Criteria*

The target population for this study included GDPs on the Northern Ireland dental list. Secondary care and private dental practitioners were excluded as the project related to Health Service referrals.

*Data Collection*

A questionnaire was designed to obtain quantitative and qualitative data from GDPs on their perceptions of managing DOAC patients in primary dental care, their awareness of the SDCEP guidelines and the factors influencing referrals. The questionnaire was initially piloted with Dental and Pharmacy staff at the Health and Social Care Board (HSCB) Northern Ireland, subsequently edited and then distributed to all 1167 GDPs on the Northern Ireland dental list with a cover letter, containing instructions and information about the study. A stamped addressed envelope accompanied the questionnaires to facilitate their return. The collection, analysis and dissemination of data took place between August and December 2018.To maintain data confidentiality, a central location was used for the distribution and return of questionnaires. The addresses and names of dental practitioners were placed on envelopes by HSCB staff to ensure no traceability of subjects by the research team. Informed consent was gained from GDPs for participation.

Raosoft®11sample size calculator was used to determine the sample size required, based on parameters such as desired confidence level, total population size, response distribution and the tolerated margin of error. The acceptable parameters of confidence level required was set at 95%, response distribution at 50% and a margin of error of 5%, which resulted in a minimum recommended sample size of 290.

*Data Analysis and Dissemination*

The data obtained was analysed using SPSS® statistical software.12 Frequencies were used to describe one variable and crosstabulation later employed to describe the relationship between multiple variables. A Cronbach’s alpha test was used to test reliability of the data. Pearson’s Chi-Square test was used to analyse the degree of significant correlation between categorical data variables at ordinal and nominal level. A p value was obtained to determine if a statistically significant relationship was present between variables. Qualitative analysis was used for open answered questions with free-text responses and main themes outlined as they emerged.

**Results**

344 of the questionnaires returned were suitable for analysis, giving a response rate of 30%. Seven questionnaires were excluded as they were incorrectly completed. The response rate achieved resulted in a margin of error of 4.44% and a confidence level of approximately 97.3 %. An alpha coefficient of 0.842 (Cronbach’s alpha test) suggested good internal consistency.

*Awareness of the SDCEP guidelines*

The majority (83.7%, n=288) of GDPs in the sample were aware of the SDCEP guidelines. However, 24% (n=82) of those aware of the guidance were unaware that they had been endorsed by the DoH Northern Ireland. Figure 1 shows the most common sources by which GDPs became aware of the guidance.

Insert Figure 1

*Figure 1: Range of sources by which GDPs became aware of the SDCEP guidelines for managing DOAC patients in primary care.*

83.6% of GDPs (n=292) indicated that the SDCEP guidelines increased their ability to treat patients taking DOACs in primary care, in comparison to 3.4% (n=10) who felt that they did not and 13% (n=38) who were undecided on the issue.

*Self-rated level of DOAC knowledge among GDPs*

Respondents were asked to rate their own knowledge of DOACs on a five-point scale ranging from poor to excellent. Overall, 36.3% (n=125) rated their DOAC knowledge as poor to fair, while 63.7% (n=219) rated their knowledge as good to excellent. Figure 2 shows the comparison between GDP DOAC knowledge rating and their confidence in managing DOAC patients in primary care. As DOAC knowledge increased, GDPs were less likely to refer more complex procedures to secondary care (p=0.001).

Insert Figure 2

*Figure 2: Comparison between GDP DOAC knowledge rating and their confidence in the management of dental procedures for DOAC patients with a bleeding risk in primary care*

*Management of DOAC patients in primary dental care*

While 98% (n=337) of GDPs felt that DOAC patients could potentially be managed in primary care, only 18.3% (n= 63) felt that this was possible given the current level of skill, training and resources. 28.2% (n=97) felt additional training was required, while 18.9% (n=65) felt that increased awareness of the SDCEP guidance was necessary. The majority (32.6%, n=112) felt that management in primary care would require a combination of both increased SDCEP guidance awareness and further training. 2% (n=7) felt that all patients taking DOACs should be referred to secondary care. Figure 3 shows the suggestions made by GDPs to facilitate the management of DOAC patients in primary care.

Insert Figure 3

*Figure 3: Range of options selected by GDPs to enable management of DOAC patients in primary care*

*Referral of patients taking DOACs to secondary care dental settings*

80% (n=275) of the GDPs sampled reported referring DOAC patients to secondary care. Of these referrals, 88.4% (n=243) were classified as high-risk procedure referrals, 7.3% (n=20) as low-risk procedure referrals patients and in the remainder of cases (4.4%, n=12), the GDP was unaware of whether or not the patient was taking DOACs. Figure 4 shows the variety of services to which GDPs have referred DOAC patients.

Insert Figure 4

*Figure 4: Services to which GDPs have referred DOAC patients*

Respondents were asked to provide their reasons for referring DOAC patients to secondary care. 45.3% (n= 129) of GDPs expressed the view that secondary care settings are better placed to manage these patients, while 20.4% (n=58) cited inadequate experience. 13.3% (n=38) reported referring due to potential complications.

*Comparison of Low-Risk and High-Risk Procedures*

GDPs were asked to quantify how many low and high-risk procedures, as classified by the SDCEP guidance that they carried out on a monthly basis. Tables 2 and 3 shows the number of low and high risk-procedures respectively carried out by GDPs per month.

Insert Tables 2 and 3

*Table 2: Number of low-risk procedures carried out by GDPs per month*

*Table 3: Number of high-risk procedures carried out by GDPs per month*

GDPs with greater levels of experience with high-risk procedures were less likely to refer DOAC patients to secondary care (p=0.001), while those with lower self-reported confidence levels in the undertaking of surgical extractions were more likely to refer (p=0.014). (Fig. 5)

Insert Figure 5

*Figure 5: Comparison of GDP self-rating for complex extractions with number of referrals of DOAC patients to secondary care*

*Significance of gender*

Of the total 344 respondents, 149 were male and 195 were female. Female GDPs were more likely to be aware of the SDCEP guidelines than their male counterparts (p= 0.004). 81.5% (n=159) of female respondents felt that the guidelines were easy to use, in comparison to 67.8% of males (n=101).

*Additional Comments*

Four GDPs felt that patients should be made aware of the risks associated with dental procedures when taking DOAC medications, while seven mentioned that a secondary care contact in the event of concerns/complications could be a useful resource. Two GDPs made comments about the fear of legal implications being an influencing factor on the willingness of GDPs to manage these patients in general practice.

**Discussion**

The vast majority of GDPs (83.7%, n=288), in Northern Ireland are aware of the SDCEP guidance on the management of patients taking anticoagulant or antiplatelet drugs. The majority (98.0%, n=337) believe that patients taking DOACs could potentially be managed in primary care, subject to the provision of appropriate training and increased awareness of SDCEP guidelines.

While the results of the study have provided interesting data on GDPs’ perceptions of the management of DOAC patients and identified strategies to facilitate primary care management, a number of limitations exist. Given the typically low response rates to postal questionnaires, a satisfactory response rate of 30% was achieved, although this still resulted in a relatively small sample size of 344 GDPs. Questionnaires may also have been returned on behalf of dental practices, rather than individual practitioners. Therefore, the findings may be representative of the views of more than 344 GDPs. The potential for response bias in those who opted to complete the questionnaire must also be considered. The self-reporting of data may also have been subject to recall bias, while the self-rating of DOAC confidence and knowledge levels are subjective measures. A number of returned questionnaires were incorrectly completed and therefore could not be included in the analysis. In addition, a ‘multi method approach’ combining questionnaires with interviews is often advocated for this type of study and may have been a useful approach to adopt. 13 However, due to financial and time constraints, this approach in this instance.

The vast majority of reported referrals made to secondary care were for procedures classified as those at higher risk of postoperative bleeding complications in accordance with the SDCEP guidelines (Table 1). The collected data revealed the sampled GDPs carry out relatively small numbers of these procedures per month, suggesting that a combination of a lack of confidence and experience with high risk procedures could be contributing to the high incidence of referral of DOAC patients for higher-risk procedures. This would correlate with the findings of some of the studies previously referenced,9,10 which suggested that 69% of referrals to secondary care oral surgery services were based on anticipated surgical difficulty, while other contributory factors included complex medical histories, primary care practitioners who did not carry out surgical procedures and a lack of oral surgery experience during undergraduate training among recent dental graduates.8,10 This is also supported by the finding of this study which showed a statistically significant relationship between increasing experience of GDPs in higher-risk procedures and decreasing number of referrals to secondary care (p=0.037).

Questionnaire responses revealed that 12% of the procedures referred to secondary care settings presented a low risk of post-operative bleeding complications and 4.4% of GDPs were unaware if a patient had been taking DOAC medication before referral. This highlights the potential for inappropriate referrals to secondary care settings. Inappropriate referrals represent a significant problem within the healthcare system, with significant financial implications. The purpose of the SDCEP guidelines is to enable provision of care in the most appropriate setting. While the SDCEP guidelines clearly outline recommended protocols for the management of DOAC patients, it is clear that the publication of such guidance, as an isolated measure, is insufficient in ensuring that these recommendations are fulfilled.

A further consideration regarding the perceived reluctance of GDPs to manage DOAC patients in primary care is the lack of high-quality evidence on the bleeding risks associated with dental procedures in DOAC patients and on the continuation or interruption of DOAC doses for clinical procedures. The SDCEP guidance document states that the recommendations made are conditional and that decisions to interrupt anticoagulant medication are based on very low quality evidence.7 The recent introduction of DOACs and the resultant uncertainty regarding their effects is likely to have had an adverse impact on GDPs perceptions of their own ability to manage these patients in primary care. The lack of availability of reversal agents to counteract the anticoagulant effects of DOACs is also likely to represent a major concern for dental practitioners.

The SDCEP guidelines outline clear protocols for the primary dental care management of DOAC patients. However, the guidance also stipulates that dentists must use their own judgement to determine whether they are sufficiently skilled to complete the procedure and manage consequent peri-operative bleeding. It is clear that GDPs need to be adequately supported to realise this goal. Merely being aware of the guidelines does not support the implementation of the recommendations on a practical level, without corresponding training in their use and relevant clinical experience in their application.

The fear of litigation was also reported as a key factor influencing referrals.  Cases resulting in litigation have been described in a study by Wahl et. al which concluded that, to minimise the risk of such occurrences, dentists have an obligation to consult prescribing doctors and to educate patients on the bleeding risks associated with dental procedures.14

A number of GDPs also felt that a local pharmacy, HSCB, or secondary care advisory contact would support the management of these patients in primary care. This finding is supported by those of a previous study conducted by Lusk et. al which concluded that periprocedural decisions regarding DOAC patients should involve a multidisciplinary approach.15 The significance between female GDPs and increased awareness of both the SDCEP guidance and its endorsement by the DoH NI correlates with the findings of previous studies, which suggest that female practitioners are more likely to provide guideline concordant care than their male colleagues.16,17  In addition, it has also previously been reported that males are more likely to have greater self-confidence and engage in more risk taking behaviours, females  are more likely to exercise caution when performing challenging procedures through carrying out research or consulting guidelines.16,17

A joint professional letter from the Chief Dental Officer and the Chief Pharmaceutical Officer was issued to all Health Service dentists in December 2017 endorsing the SDCEP guidelines, in addition to information provided through the GDS News Sheet. However, almost a quarter of GDPs who reported being aware of the SDCEP guidelines were unaware that this guidance had been endorsed by the DoH Northern Ireland. This would suggest that more effective collaborative approaches between the HSCB and GDPs would contribute to increased clarity among GDPs on locally approved management strategies.

A study published in 2017 found an increase of 58% in the number of first-time oral anticoagulants prescriptions during the period 2009 to 2015. It was found that new DOAC prescriptions increased dramatically during that period, with DOACs accounting for 56% of first-time oral anticoagulant prescriptions in 2015.4 With the increasing prevalence of thromboembolic disease3 and the emerging trend in the prescription of DOACs, GDPs are likely to witness an increase in DOAC patients presenting to primary care for routine dental procedures. Addressing the concerns of GDPs in relation to the management of these patients is essential to enable the provision of safe and appropriate care.

**Conclusions**

This study has shown that, while most GDPs in Northern Ireland are aware of the SDCEP guidelines on the management of patients taking anticoagulant and antiplatelet drugs, a large majority have referred DOAC patients to secondary care settings for treatment, in contradiction to the recommendations of the guidelines. This has been attributed to a lack of confidence and experience in managing these patients successfully in primary dental care.

The findings of this study should be used to address the concerns of GDPs within Northern Ireland relating to the management of patients taking DOACs in primary dental care. The issues raised may well be universal to other regions. Enhanced adherence to the SDCEP guidance should enable the provision of efficient and timely care in the most appropriate setting for these patients, as well as avoiding the over-burdening of limited and costly secondary care resources.

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