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Abstract

Objective: To explore community pharmacists' understanding and opinions in relation to prevention of fungal colonisation of voice prostheses amongst laryngectomy patients.

Method: Semi-structured interviews were conducted on a purposive sample of 12 community pharmacists from the North of England. Interviews were undertaken until data saturation was reached and responses were transcribed verbatim and analysed using a thematic approach.

Key findings: Six themes emerged from the data analysis. These were: terminology confusion about laryngectomy, stoma and voice prostheses; smoking as a risk factor for the development of laryngeal cancer; using nystatin to prevent biofilm formation; counselling information related to nystatin; prescription intervention and additional education in relation to laryngectomy. The theme of counselling information related to nystatin use and additional education was a key finding: our data show that when dispensing nystatin to patients with a voice prosthesis, community pharmacists would either give no advice related to medication use or would give incorrect advice that may lead to premature prosthesis failure amongst this patient group.

Conclusion: This study highlights that community pharmacists lack understanding in relation to laryngectomy and are unaware of the off-label doses and administration methods of the drugs (specifically nystatin) used to prevent fungal colonisation on voice prostheses. Additional information sources – possibly obtained through the local Speech and Language Therapy Department – in the form of an educational leaflet would be perceived as a valuable resource to support community pharmacists who are required to manage these patients in the community.

Keywords: Head and neck cancer, community pharmacists, laryngectomy, off-label prescribing, voice prosthesis.

Introduction

Head and neck cancer encompasses a range of tumours that develop in the head and neck, including the nasal cavity, sinuses, lips, mouth, salivary glands, throat or larynx; they are now the sixth most common cancer in the world, causing an estimated 350,000 deaths per year. Worldwide, tumours of the oral cavity and pharynx are the most common type of head and neck cancer at around 480,000 cases per year, while cancer of the larynx results in an estimated 160,000 cases per year.[1] Similarly, in England, cancers of the oral cavity and pharynx are the most common forms of head and neck cancer, followed by cancer of the larynx – a cancer that is linked to smoking and excessive alcohol intake. Between 2002 and 2006 the incidence of laryngeal cancer in the North East region was an age-standardised rate of 4.39 per 100,000 with an age-standardised mortality of 1.36 per 100,000.[2] During 2009/10 around 570 laryngectomies were performed in England, the majority of which were to treat advanced laryngeal cancer.[3]

Locally advanced laryngeal cancer is managed by a total laryngectomy, a procedure where the entire larynx is removed. This procedure is relatively successful, although removal of the vocal cords poses the obvious problem of a patient being unable to speak after the operation. At present, a voice prosthesis can be inserted into the patient's neck, which helps with voice restoration. Unfortunately, all voice prostheses can, over time, fail and leak, which, if left unchanged, can lead to the development of aspirational pneumonia – a potentially fatal complication.[4] On occasion, voice prostheses can fail prematurely, which not only increases the risk of developing aspirational pneumonia, but is also inconvenient for patients (due to frequent visits to hospital to get the prosthesis replaced) and expensive to the healthcare provider (one prosthesis can typically cost around £200 before taking into account the clinic time required to fit it). The premature 'failing' of voice prostheses has therefore been the subject of considerable investigation, leading to the thought that formation of a biofilm (colonisation of fungi and bacteria) on the oesophageal side of the prosthesis contributes to this failure.[5][6]

Candida albicans, a naturally occurring fungal species in the body, is the most prevalent isolate found on voice prostheses and is considered one of the main causes of premature prosthesis failure.[7] As a result, patients with voice prostheses use antifungal agents to prevent biofilm formation and, ultimately, premature prosthesis failure. Typically, high doses of antifungal agents are used which constitutes 'off-label' use of the drug. Off-label use refers to when a licensed medicine is prescribed outside its marketing authorisation and should only be considered when there is no licensed medicine available to meet the clinical need of the patient. Community pharmacists play a crucial role in the supply of medicines off-label and have a responsibility to make prescribers aware that they are prescribing a medicine outside of its marketing authorisation.[8] Doctors also have a responsibility to provide patients with sufficient information about the medicine so an informed decision can then be made by the patient.[9] Nystatin liquid is used off-label at a dose of 500,000 units twice daily to prevent colonisation of *Candida albicans* on the voice prosthesis. The patient is advised to hold the nystatin in their mouth for six to eight minutes before swallowing and then have nothing to eat or drink for one hour afterwards. Therefore both the dose and the method of administration are different from the licensed particulars.[10][11] This regimen should be undertaken by patients on a daily basis throughout their life with a voice prosthesis to reduce the probability of biofilm formation (and ultimately valve failure). Unfortunately, information related to this 'off-label' use (and associated dose) is not readily available; it is not listed in the British National Formulary (BNF) or the Summary of Product Characteristics (SPC).[12][13]

Patients who have undergone a total laryngectomy are, in part, managed in the community in partnership with speech and language therapists in secondary care. Community pharmacists are involved in the care pathway of these patients with responsibility for supply of laryngectomy appliances, such as cleaning brushes and protectors as well as the drugs used for antifungal prophylaxis.[14]

Aim of the Study

To explore community pharmacists' understanding and opinions in relation to prevention of fungal colonisation of voice prostheses amongst laryngectomy patients. As the North of England has the highest rates of laryngeal cancer in England, it was decided to conduct the study in this region.

Methods

Design

This study used qualitative methods, in the form of semi-structured interviews to examine community pharmacists' understanding and opinions of issues related to the treatment of laryngectomy.

Participants

Community pharmacists who work in the North East of England were invited to take part in the study.

Sample

All community pharmacies within the geographical area with details of the study were approached in writing to invite them to participate in the study ($n = 95$). Those who responded positively were contacted and given further written information regarding the study.. To achieve maximum variation in our sample based on their time spent in practice, 20 community pharmacists were invited for interview. The researcher (SK) carried out the interview at a location chosen by the community pharmacist. Each interview lasted approximately 30 minutes.

Interview schedule- content and development

The interview questions were developed after several meetings with speech and language therapists based at a regional hospital in the North of England. The interview questions were piloted with two community pharmacists and, based on feedback, were modified for the main set of interviews. The understanding and opinions of community pharmacists in relation to laryngectomy and fungal colonisation on voice prostheses are unknown, and we were interested in finding out whether there

was any role played by time spent in practice.

Semi-structured interviews commenced by asking the interviewee about their training and experience as a community pharmacist. After this, the interviewee was asked a set of open-ended questions and prompted when appropriate to allow further discussion and elaboration of points:

1. What knowledge do you have concerning total laryngectomy as a surgical intervention or laryngectomy patients as a group?
2. Do you know what a voice prosthesis is, and how a patient may end up with a stoma, or a voice prosthesis inserted within the neck?
3. Can you explain what a stoma and voice prosthesis is in your own words?
4. What do you think are the most significant risk factors contributing to laryngeal cancer?
5. What drugs are used to prevent fungal growth on a voice prosthesis?
6. If you were presented with a prescription for nystatin liquid at a dose of '5 mL twice daily', how would you respond?
7. What counselling or advice would you give to a patient with a voice prosthesis taking an antifungal to prevent fungal colonisation?
8. Do you think extra training should be given to community pharmacists when managing laryngectomy patients fitted with a voice prosthesis?

Interview conduct

Interviews were taped and then transcribed verbatim; handwritten observational field notes were recorded electronically. The typed transcript was reviewed by the researcher and compared with the field notes made during the interview to ensure meaning had not been lost in the transcription process. The data were then analysed using a thematic approach consisting of the following stages: familiarisation with the data by re-reading of the transcripts; generating initial codes, searching for themes; reviewing themes, defining themes and reporting themes.[15] This process was led by the

primary researcher (SK), but was reviewed by the first author (AT) who read transcripts, discussed and confirmed coding and interpretation.

The project was certified for ethical approval by the senior researcher (AT) in accordance with the University of Sunderland Ethics Committee.

Results

Twenty community pharmacists were invited to participate and 12 (7 female) agreed to take part (60%). The mean number of years qualified as a pharmacist was 16 (standard deviation 12; range 3 – 41 years). Data collection took place between February and May 2012 continuing until data saturation was reached.

The following six themes were identified in the transcripts: terminology confusion about laryngectomy, stoma and voice prostheses; smoking as a risk factor for the development of laryngeal cancer; using nystatin to prevent biofilm formation; counselling points; prescription interventions and additional education.

1. Terminology confusion about laryngectomy, stoma and voice prostheses

Participants conceded they did not know what the terminology meant or they identified it in other contexts not related to voice prostheses or laryngectomy.

A stoma is just in the lower part of the abdomen where faeces is excreted from. Pharmacist B, 5 years qualified.

A stoma is part of a plant cell, isn't it? Pharmacist G, 17 years qualified.

One participant reported they had patients to whom they dispensed laryngectomy appliances, but did not specifically know what a stoma or a voice prosthesis was.

Yes well I've got two patients in the community that I supply laryngectomy equipment to... no, I couldn't tell you what a voice prosthesis is. Pharmacist E, 7 years qualified.

In addition, participants also appeared to lack knowledge regarding laryngectomy as a procedure and as a patient group. For example, their answer for some questions, although confident, revealed terminology confusion – one participant thought laryngectomy was reversible. In this case, it is possible the participant confused a laryngectomy with a tracheostomy, which is a reversible procedure.

Well, I deal with a couple of patients in my pharmacy, in regards to supplying devices I do have fairly good knowledge base on that front - my patients include one child with [a] reversible laryngectomy. Pharmacist E, 7 years qualified.

Observational behaviours identified from the field notes suggested that some participants initially appeared confident when first asked about laryngectomy but, when asked further questions to probe knowledge, they became uncomfortable and anxious.

2. Smoking as a risk factor for the development of laryngeal cancer

This theme expressed the general consensus that smoking is a risk factor for the development of laryngeal cancer, although in the majority of cases, the participants were not confident in their responses and used terminology such as ‘probably’, ‘guess’ and ‘presume’.

I'm not sure but I would guess that smoking would have a part to play in it. Pharmacist C, 8 years qualified.

One participant mentioned other risk factors for the development of laryngeal cancer such as alcohol, genetics and environmental factors. This participant was also more confident in their answer and used the term ‘definite’.

Well, I think smoking is a definite cause as well as alcohol. Genetics may also play a part in it and chemicals so when patients may possibly breathe in toxic material from a nuclear power plant that contributes to cancers developing. Pharmacist A, 8 years qualified.

3. Using antifungals to prevent biofilm formation

All participants suggested that antifungal medication could be used to prevent fungal growth on voice prostheses. The participants indicated that a wide range of antifungal medication could be used for this purpose and included the azoles (or the imidazoles), amphotericin and nystatin. Participants who had experience with this patient group were more confident in their answers – with one giving a typical dosage used, compared to other participants with less experience. A word used frequently by participants when describing this association was ‘assume’ which was not observed as a reflection of the uncertainty in relation to the efficacy of the prophylactic use of antifungals in biofilm formation, but rather an expression of lack of confidence.

They use nystatin 5 mL four times a day. One of my patients is on that and I had to ring Medicines Information to confirm the dose. That is what the hospital use for the prevention of fungal growth. Pharmacist A, 8 years qualified.

I have not had any experience of it, I wouldn't know. I would assume it's the regular antifungal – the azoles – but honestly, I don't know. Pharmacist H, 15 years qualified.

Only one participant mentioned the route of drug administration when using the antifungal medication to prevent biofilm formation on voice prostheses. This participant differentiated between topical and systemic application and suggested miconazole gel could be used for topical application, while fluconazole could be used for systemic administration.

If topical treatment was warranted, perhaps miconazole? Or if systemic is needed something like fluconazole? Pharmacist J, 3 years qualified.

4. Prescription interventions

All of the participants in the study group, if presented with a prescription for nystatin, at a dose of 500,000 units twice a day, recognised that this was not the licensed dose and would consequently

either check this with the patient or the prescriber. Only one of the participants additionally recognised that this was a typical dose of nystatin used for laryngectomy patients to prevent biofilm formation on voice prostheses.

Well prior to having this patient I have at the minute, I would have thought what on earth is happening but, because I've got that dose, I would check if they have had a laryngectomy. But when I initially got that prescription, first of all, I phoned the GP. Pharmacist E, 7 years qualified.

When talking about the prescription interventions, the observations in the field notes suggested that the participants appeared to be more confident and assertive and used terminology such as 'certainly', 'definitely' and 'find out exactly'.

5. Counselling in relation to nystatin use for laryngectomy

A theme emerged that community pharmacists would decline to offer additional advice to laryngectomy patients when using antifungals as biofilm prophylaxis in comparison to patients receiving antifungal medication for other complaints.

I don't think any new advice should be given. Pharmacist B, 5 years qualified.

The majority of the participants felt that providing advice to patients was important, but patients were counselled according to medication type rather than according to individual-patient need or the indication of use. For patients receiving nystatin as antifungal prophylaxis, counselling would focus on 'the standard information', which included the importance of using the medication topically. Some participants referred to patients using the nystatin for several days after the lesions have healed suggesting that the advice is primarily aimed at patients using it for the treatment of oral candidiasis demonstrating an unawareness of the specialist use of nystatin.

With that drug [nystatin] you would suggest they continue on for a period of a couple of days

after it has cleared to make sure it has cleared. Pharmacist C, 8 years qualified.

Two of the participants declined to offer additional advice to patients when dispensing antifungal medication and therefore would not offer any unless specifically asked.

Unless specifically asked by a patient, I wouldn't normally give any advice. Pharmacist L, 37 years qualified.

6. Additional education

Some of the participants expressed a lack of confidence in dealing with laryngectomy patients and recognised they lacked knowledge in this area. In addition, some felt that as they were not from a 'hospital' or 'clinical' environment, they had little experience of dealing with this patient group. One issue that emerged in several interviews was community pharmacists made a clear distinction between themselves working in community in primarily a dispensing and information giving capacity, in comparison to hospital pharmacists who they felt had more of a clinical role. Participants perceived hospital pharmacists as having greater clinical knowledge than community pharmacists and often used the words 'hospital' and 'clinical' interchangeably.

I am not from a clinical or hospital environment so I haven't had much experience really.

Pharmacist D, 16 years qualified.

The participants felt that encountering patients with laryngectomy in the community was relatively 'rare', additional training for treatment of laryngectomy prostheses would not be valuable or even warranted. In addition, several of the participants also perceived patients with voice prostheses as 'experts' and valuable sources of information in relation to laryngectomy. However, despite this, all participants wanted a 'quick' information source they could refer to regarding laryngectomy patients and the drugs used to prevent fungal colonisation on voice prostheses.

I've been working in practice for over a decade and never had it affect me as a pharmacist. I

think, however, something you can quickly refer to should be available but should everyone be subjected to training? No. Reading something – a leaflet – is always a good source to have. Pharmacist H, 15 years qualified.

Discussion

Summary of the main findings

In summary, this study found several issues emerged from interviews with community pharmacists regarding laryngectomy. These issues included confusion about terminology related to laryngectomy, stoma and voice prostheses; inconsistency or uncertainty around the use of nystatin to prevent biofilm formation; provision of standard counselling for nystatin use, rather than tailored for voice prostheses; and a desire for additional information on off-label doses and administration methods of the drugs used to prevent fungal colonisation on voice prostheses.

Strengths and Limitations

This is one of the first studies to examine community pharmacists' understanding opinions of issues related to the treatment of laryngectomy. Community pharmacists have an important role in the management of laryngectomy and voice prostheses; this study has helped to clarify issues in relation to this support. Although voice prostheses for laryngectomy are not common, the results of this study may provide suggestions for the needs of community pharmacists in relation to the care of patients having other uncommon conditions. We believe our results are robust and have important implications for the treatment of laryngectomy patients with voice prostheses by community pharmacists, and perhaps more widely in relation to community pharmacists delivering specialist clinical services. However, only community pharmacists from the North of England were surveyed. In addition, the interpretation of the observed mannerisms of the participants was entirely that of the researcher [SK] and not independently checked. Generalisation of this work to all community pharmacists in England and more widely should therefore be made carefully.

Relation to prior work and implications for policy and practice

A key finding was that when dispensing antifungal medication to patients with a voice prosthesis, some of the community pharmacists would not give any advice regarding the use of the medication. These pharmacists had been registered for the longest period of time amongst all of the participants in the study. Indeed, one of the key standards of performance as outlined by the pharmacy regulator in the UK, the General Pharmaceutical Council (GPhC), is to 'be satisfied that patients or their carers know how to use their medicines'.^[16] Clearly, to meet these standards communicating with and counselling patients about their medicine(s) is essential, particularly when a medicine has been prescribed off-label. There is no differentiation within this as to how rarely one may encounter a particular situation in practice and thus all patients should expect to receive the same standard of care.

A possible reason for the observation of differences in the counselling provided by pharmacists could be that the role of the community pharmacist has changed, with the emphasis taken from solely dispensing medication to a more patient-focused role.^[17] In addition to the requirements of the GPhC, and as part of the Pharmacy Contractual Framework in England, all community pharmacists are required to dispense medication and provide information and advice to ensure safe and effective medicines use by patients and carers.^[18] In view of this change in role, the training of pharmacists has also evolved, with pharmacy degrees typically having more focus on clinical content and pharmaceutical care than was previously the case. It is plausible that training given to more recently qualified pharmacists has prepared them with the skills to effectively counsel patients about their medicines, while pharmacists who have been registered longer may not have had specific training on the importance of effective counselling in terms of appropriate medicines use. While previous work has found that community pharmacists are aware of the issues that surround off-label prescribing, this knowledge appears to be gained through experience rather than undergraduate or postgraduate training.^[19] In our study, community pharmacists who have been registered the

longest amongst our sample were less likely to offer additional advice when supplying laryngectomy patients antifungals, although it is not clear if they recognised that this was an off-label use of the medication. This observation may prove to support a training opportunity for community pharmacists, but is clearly based upon our limited sample and should not be generalised without further investigation.

In general, community pharmacists would not give additional advice to patients with a voice prosthesis when using antifungals as prophylaxis against *Candida* growth beyond that given to other patients using it for the treatment of oropharyngeal candidiasis. This group included pharmacists who already dispense medication to patients with voice prostheses. These findings are of significant value as patients fitted with a voice prosthesis are advised to use nystatin twice a day for five to eight minutes following the 'swish-and-swallow' protocol.[11] This method of administration is different when compared to using it for the regular treatment of oropharyngeal candidiasis and, as such, counselling for patients (and training for staff) should reflect this difference. If the technique of administration is not periodically reinforced by community pharmacists at the time of dispensing, patients may become non-adherent, increasing the risk of prosthesis failure and, more significantly, aspirational pneumonia. In addition, for patients taking high dose nystatin as fungal prophylaxis, it would be appropriate to offer advice about oral hygiene (such as cleaning teeth/dentures before bed). Nystatin contains sugar, which can have implications for this patient group, as teeth can often be damaged as a result of radiotherapy. If patients are using nystatin immediately prior to retiring to bed without taking the appropriate actions in relation to oral hygiene, there is potential for further damage of the teeth.

Community pharmacists interviewed suggested one way to improve understanding of this patient group could be to supply information in the form of a leaflet sent directly from the Speech and Language Therapy Department, when a patient uses it to obtain their laryngectomy equipment and antifungal medication. The leaflet could contain background information to laryngectomy, give

general advice about voice prostheses (such as cleaning regimens) and provide information related to the off-label use of antifungals in this patient group.

These findings have not been reported elsewhere in the literature, although it has been acknowledged that hospital pharmacists have an important role in optimising treatment for patients with head and neck cancer, suggesting that such pharmacists may indeed have better knowledge of this patient group.[20] Hospital pharmacists, in contrast to community pharmacists, however, work as part of the wider healthcare team. Working predominantly independently, community pharmacists do not have access to as many resources as those in hospitals, such as speech and language therapy departments for advice and training in relation to this patient group. Interestingly, in our study, pharmacists working in a hospital environment were perceived as being more 'clinical' by the community pharmacists and were therefore expected to have more knowledge of laryngectomy and the drugs used in antifungal prophylaxis. This observation is timely as a recent study regarding pharmacists' perceptions of their role and professional identity showed that the role of a clinical practitioner was more prevalent in hospital pharmacists than community pharmacists.[21] In the same study, community pharmacists, despite spending time communicating with patients about medicines use, never described their work as 'clinical'. Indeed, as proposals have been made to transfer specialist clinical services from secondary to primary care (e.g. community pharmacists dispensing oral chemotherapy in primary care [22]), our observation warrants further investigation as it may prove to be a barrier for community pharmacists delivering specialist clinical services.

Conclusion

In summary, this study highlights that community pharmacists lack understanding in relation to laryngectomy and are unaware of the off-label doses and administration methods of the drugs (specifically nystatin) used to prevent fungal colonisation on voice prostheses. Additional information sources – possibly obtained through the local Speech and Language Therapy

Department – in the form of an educational leaflet would be perceived as a valuable resource to support community pharmacists who are required to manage these patients in the community.

Declarations Conflict of interest

The Authors declare that they have no conflicts of interest to disclose.

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