European Journal of Obstetrics & Gynecology and Reproductive Biology 201 (2016) 42–45

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Colposcopists' experiences of HPV Test of Cure for the follow up of cervical intra-epithelial neoplasia

Susan M. Sherman [a,*], Esther L. Moss [b], Philippa Pearmain [c], Charles W.E. Redman [d]

[a] School of Psychology, Keele University, Keele, Staffordshire ST5 5BG, UK
[b] Department of Gynaecological Oncology, University Hospitals Leicester, Gwendolen Road, Leicester LE5 4PW, UK
[c] Screening QA Service (West Midlands), Public Health England, 5 St Phillip's Place, Birmingham B3 2PW, UK
[d] Department of Obstetrics and Gynaecology, Royal Stoke University Hospital, Stoke on Trent ST4 6QG, UK

ARTICLE INFO

Article history:
Received 23 November 2015
Received in revised form 14 March 2016
Accepted 17 March 2016

Keywords:
Test of Cure
HPV
NHSCSP
Cervical screening

ABSTRACT

Objective: To survey lead colposcopists in England to explore their views on the recently introduced HPV Test of Cure (TOC) following treatment for cervical intra-epithelial neoplasia (CIN) and to determine the extent to which it has impacted their clinical practice and affected their patients.
Methods: An online survey was sent to lead colposcopists across England. Questions were asked focusing on the clinicians' confidence in the ability of TOC to guide follow up in various clinical scenarios and how the implementation of TOC had changed patient management.
Results: There was a 50% ($N = 88$) response rate. 90% of respondents indicated they were happy with the new procedure. In the follow-up questions, 20% indicated they were uncomfortable with the procedure when it was applied to women who were CIN2+ with incomplete excision at the endocervical margin. Open-ended questions elicited positive aspects of TOC including reduced follow-up, increased reassurance for patients and clinicians and a faster return to the call–recall system. Negative observations included concerns around HPV positive cases, possible false negatives and anxiety in those women who were originally subject to the pre-TOC guidelines and were now returned to call–recall "earlier" than originally indicated to them. 11% of respondents also indicated they work around the new guidelines to some extent.
Conclusion: Although clinicians are on the whole positive towards the introduction of TOC, concerns were raised which centre primarily around those patients with CIN2+ combined with positive endocervical margins, issues related to HPV positive cases and the possibility of a false negative HPV result. The possibility of patient anxiety due to return to routine screening earlier than originally expected was also identified as a concern.

Introduction

In 2011 the NHS Cervical Screening Programme (NHSCSP) announced the introduction of human papillomavirus (HPV) testing for the purposes of triage and Test of Cure (TOC). This was based on evidence from six Sentinel pilot sites. Roll out across England commenced from April 2012. Under the old guidelines, once a woman had undergone treatment for cervical intra-epithelial neoplasia (CIN) or cervical glandular intra-epithelial neoplasia (CGIN), she was followed up for at least 10 years with cervical screening at 6 months, 1 year and thereafter annually, for 9 years assuming no abnormal results occurred. After 10 years she was returned to routine recall. Under the new guidelines, 6 months after a woman has undergone treatment for CIN the HPV TOC protocol uses high risk HPV (HR-HPV) testing to evaluate whether the woman requires referral for further assessment or whether they can be discharged and recalled for screening in 3 years [1]. For CGIN two HPV TOCs were introduced in May 2014 – one at 6 months and another at 18 months after treatment.

The introduction of TOC has dramatically changed the follow up of CIN with the intention of stratifying women's risk and reducing the number of screening tests performed in the follow-up cohort. One consequence of the change however, is a greater reliance on colposcopic examination in order to exclude high-grade CIN. This creates a difficulty since colposcopy is known to miss high-grade

* Corresponding author at: School of Psychology, Dorothy Hodgkin Building, Keele University, Keele, Staffordshire ST5 5BG, UK. Tel.: +44 01782 733384.
E-mail address: s.m.sherman@keele.ac.uk (S.M. Sherman).

http://dx.doi.org/10.1016/j.ejogrb.2016.03.023
0301-2115/

disease [2] and in colposcopy following treatment the rate of cervical stenosis and unsatisfactory colposcopy increases [3]. New technologies, are being developed that may have the potential to increase the accuracy of colposcopy in the future. However, these techniques are either not approved for use in the NHS Cervical Screening Programme or are not mandated as part of the Programme and therefore have not been universally adopted by the NHS.

Cases are emerging of high grade cervical lesions in women who have previously tested negative for HR-HPV. Liverani et al. for example, found that of 134 CIN 2+ cases, 19 (14.2%) had tested HR-HPV negative [4], while Cotton et al. reported 22% of women with CIN 2+ as being HPV negative [5]. HPV negative cancers have also been reported in the literature. One European study reported that HPV testing provides 60–70% greater protection against cervical cancer compared to cytology [6]. Whilst this may well be true, Liverani observed that in that research, "only 11 out of 19 cervical cancers detected over 2.5 years after enrolment, were HPV positive at baseline" [7] (p. 85). Amongst those deemed by the authors to be prevalent by virtue of being diagnosed in the first 2.5 years of the study, 16% were HPV negative at baseline.

With the precise timeline of HPV infection still imperfectly understood [8] and the changes to the NHSCSP over the past 4 years introducing a considerable role for HPV testing in the screening programme, it would be timely to evaluate the experience of the colposcopists working under the new guidelines. The current study was conducted to investigate the impact the introduction of the TOC protocol has had on colposcopists and their views on patient management.

Materials and method

An electronic survey was conducted of all 191 lead colposcopists across England following consultation with the British Society for Colposcopy and Cervical Pathology (BSCCP). An email was sent with a link to an online 11 item self-report survey. The only demographic data collected was the region in which they worked and when their unit implemented TOC. Respondents were then asked to rate how comfortable they were with the TOC protocol in different clinical scenarios on a 5 point Likert scale (1 – completely uncomfortable, 5 – completely comfortable). Further items, were open-ended questions, and asked respondents to give their views on TOC and to comment on any positive or negative aspects from the point of view of the clinician, patient and service delivery.

Results

There was a response rate of 50% ($N = 88$).[1] 4% ($N = 4$) adopted the procedure as part of the pilot before April 2012, 40% ($N = 35$) adopted it in 2012, 48% ($N = 42$) adopted it in 2013 and 8% ($N = 7$) adopted it in 2014.

When asked how comfortable they were with the guidelines, the vast majority (90%, $N = 79$) indicated with a score of 4 or 5 that they were comfortable. Only 2% ($N = 2$) indicated that they were not comfortable with a score of 1 or 2. 3% ($N = 3$) declined to answer the question and 4% ($N = 4$) gave a neutral 3 response.

Question 4 probed the responses to question 3 by asking the same question broken down by patient classification. The responses are shown in Table 1.

[1] Although the survey was successfully (i.e., no out of office/bounce back messages received) sent to 176 of the 191 email addresses, we are aware that some of these will not be current due to the unavailability of revised up to date email lists. In addition some clinicians may have been unable to respond due to local IT security measures – one clinician contacted the first author to indicate that s/he was unable to access the survey for this reason. Therefore the response rate of 50% is likely to be an underestimate.

Respondents were asked what they felt the positive and negative aspects of TOC were. These were open ended questions and responses were grouped into categories. Positive aspects of the procedure were identified as follows: less follow-up including attendant reduction in non-compliance and reduced patient anxiety associated with repeat medical tests (44%, $N = 37$), reassurance for patient and/or clinician (30%, $N = 25$), faster return to call–recall system (29%, $N = 24$), evidence-based practice (10%, $N = 8$) and reduced workload/cost saving (7%, $N = 6$). There were comments by 10 respondents ($N = 12$) that did not fall into these categories. One respondent stated that "Encourages better cooperation between community (smearing) and Hospital (colposcopy). Allows a proper community/hospital screening program to be developed, used and audited." Two comments concerned the nature of the test – one saying it was easier to get a result, whilst the other commented it was useful where the cervix is very scarred. One respondent stated that even when cytology is subsequently abnormal at 3 years it can still be treated. Other comments included that the test provides additional information ($N = 2$), it could be done by a GP ($N = 1$), after seeing a round of these patients, no concerns ($N = 1$) and it identifies the major HPV serotypes implicated in CIN. One commented that "It also prompt referrals for the BNC with HGHPV +ve".

82% of respondents ($N = 72$) identified negative aspects of TOC. These were categorised as follows: concerns around HPV positive cases, including patient anxiety and concerns about discharging these patients (28%, $N = 20$); concerns about false negative results (11%, $N = 8$); anxiety of women who had been treated under the old guidelines and were returned to 3 yearly recall "early" (11%, $N = 8$); a feeling that more evidence was needed (8%, $N = 6$); concern that something might be missed (7%, $N = 5$); general patient anxiety (7%, $N = 5$); an increase in workload/colposcopist responsibility (7%, $N = 5$); issues around explaining HPV to patients (6%, $N = 4$); confusion in primary care (6%, $N = 4$); concern about the quality of the cervical sample taker/the screening test missing something (6%, $N = 4$) and the time needed for patients/GPs/colposcopists to adjust to the change (4%, $N = 3$). There were 10 uncategorised comments as follows: "CIN1 not treated and just followed up with smear after 3 years"; "Does not treat HPV"; "having to explain to women why they have a "new" lesion when their next smear is positive... some women are going privately to have another smear test, another HPV test..."; "HPV testing is not comprehensive enough; not all high risk serotypes are tested for"; "If the loop has come back as negative and MDT has downgraded the smear later, we cannot discharge the patient on open exeter without doing a TOC"; "not sure about glandulars being included"; "splitting hairs"; "unnecessary colposcopies"; "The treatment is for CIN and not for HPV. Patients are still at risk of recurrence, 3 year recall is too long"; "very difficult in older women, whom 'normal recall' is no further smears if ~60 yrs old or more – this is not appropriate as still at risk for ~10–20 yrs, but won't get any more smears".

Respondents were asked whether they thought the procedure had affected their patients. 64% ($N = 56$) indicated that it had, 20% ($N = 18$) indicated that it had not, whilst 16% ($N = 14$) were not sure. Those who responded 'yes' indicating that they felt it had affected their patients were asked to elaborate further. 44 respondents (79%) made positive comments about the procedure, 22 (39%) made negative comments and 1 (2%) was neutral. Most of the comments repeated the positive and negative aspects of the procedure outlined above, however new observations included the fact that it provided an opportunity to educate women about HPV ($N = 1$), that it increased patient satisfaction ($N = 1$), "we have gone off protocol for a number of older women and picked up an early cancer at 12/12 smear in one" ($N = 1$), "few patients request more frequent smears and some of the GP's/colposcopist provide it privately which is confusing" ($N = 1$).