

Health related quality of life (HRQoL) in cervical carcinoma: Clinical significance and methodological issues



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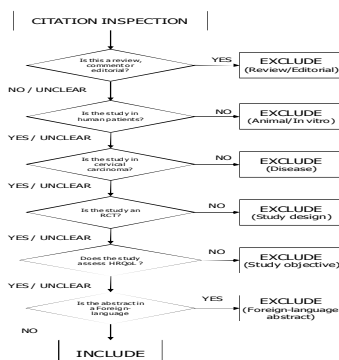
Introduction

Cervical cancer is the second most common type of cancer among women [1]. Cervical cancer forms in tissues of the cervix. It is usually a slow-growing cancer that may not have symptoms but can be found with regular Pap tests [2]. The primary underlying cause of cervical cancer is infection with the sexually transmitted human papillomavirus (HPV) [3]. Survival of patients with cervical carcinoma has been significantly prolonged in the last two decades as a consequence of early diagnosis and new therapeutic strategies. The therapy is associated with increased toxicity which in turn makes QoL an important parameter [4]. Further, the QoL measurement tools have been found to exhibit some methodological issues with respect to their use and interpretation. In the present study, the use of HRQoL instruments and related issues with clinical implementation of HRQoL have been discussed.

Methods

- Medline, Embase and Cochrane Central Register of Controlled Trials were searched from inception to 2010 for RCTs investigating HRQoL in cervical carcinoma.
- Studies were assessed for inclusion/exclusion by two independent reviewers based on a pre-specified protocol (Figure 1).
- A two-stage data extraction process was used to capture key outcomes including HRQoL differences between treatment arms, method of statistical analysis for HRQoL data, clinical significance of changes in HRQoL, HRQoL assessment, and reporting of baseline compliance rates, rates of attrition.
- At all steps any discrepancy was resolved by a third reviewer.

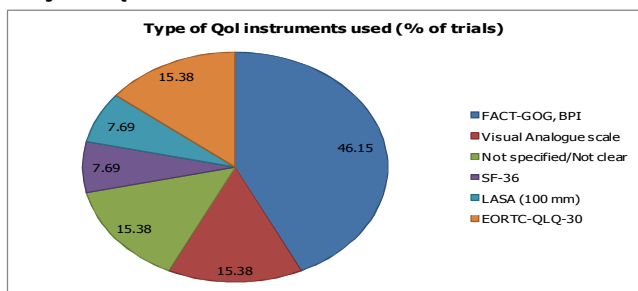
Figure 1: Flow diagram for inclusion



Results

- Of the 96 RCTs identified, 13 RCTs enrolling 2644 patients met the inclusion criteria.
- Ten trials compared different chemotherapy regimens in the first to third line of treatment.
- QoL instruments used included Functional Assessment of Cancer Therapy (FACT-G), cancer specific European Organization for Research and Treatment of Cancer-Quality of Life Questionnaire-Core 30 (EORTC QLQ-30), SF-36, and Linear Analogue Scale Assessment (LASA 100 mm) either alone or in conjunction with the Brief pain Inventory (BPI) as shown in Figure 2.
- HRQoL was assessed as a primary objective in one trial (Figure 3) [5]. However HRQoL results were reported adequately in 61% of the trials.
- Prognostic value of QoL was assessed in only two trials [6;7].
- Methodological issues identified were lack of a priori hypothesis (92.30% studies), and lack of methods to deal with the missing data (85% studies). Other issues included inadequate instructions on instrument administration, variability in time points of administration of a tool and patient non-compliance, reported in ~60% studies (Figure 4).
- Statistically significant differences in HRQoL between treatment groups were studied in 69% studies, but the clinically meaningful difference was examined in only one study.

Figure 2: HRQoL instrument used in clinical trials



Conclusions

HRQoL is widely included as an outcome in the studies investigating therapies in cervical carcinoma but the clinical relevance of these outcome measures is not visible in practice. The methodological shortcomings in the assessment and analysis of HRQoL outcomes should be looked into, to derive clinically meaningful and correlating evidence.

Figure 3: HRQoL as a primary objective in clinical trials

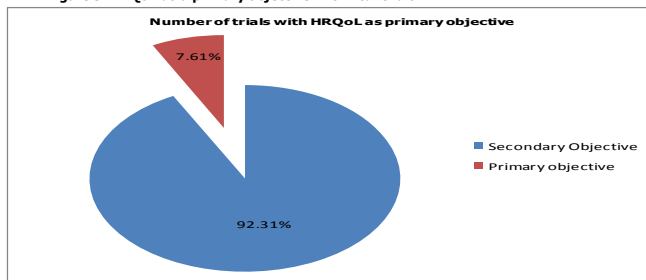
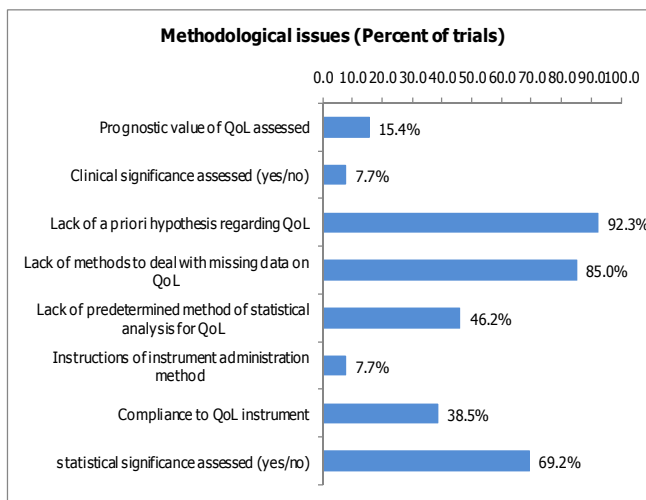


Figure 4: Clinical relevance and methodological issues in clinical trials



References

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