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A “WAKE-UP CALL” FOR ROUTINE MORBIDITY AND MORTALITY REVIEW MEETINGS PROCEDURE AS PART OF A QUALITY GOVERNANCE PROGRAM IN RADIOTHERAPY DEPARTMENTS: RESULTS OF THE PROUST SURVEY

Running title: Morbidity meetings after radiotherapy

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Abstract

Purpose

Morbidity and mortality review (MMR) meetings in Radiotherapy (RT) departments aim to monitor radiation-induced toxicities and identify potential factors that may be correlated with their development and severity, particularly treatment planning errors. The aim of the PROUST Survey was to make an inventory of existing MMR procedures and to describe their procedures.

Materials and Methods

The link to the web-questionnaire of the PROUST survey was sent to 351 radiation oncologists working in 172 centers. The questionnaire included items of organization, frequency, membership, governance, reasons for non-implementation of MMR and interest in its creation.

Results

As of July 2017, we had received 108 responses from the 172 centers, 107 of which were completed for analyses. All centers declared that they had initiated a quality assurance program in the department, including implementation of feedback committees (FBC) dedicated to the registration, analysis and correction of precursor events. Less than half the centers (47%) had implemented MMR procedures. However, there was significant confusion with FBC in the large majority of them. MMR were organized every six and 12 months in 21% and 15% of the centers, respectively. In 60% of the centers, toxicity \geq grade 3 was the main reason for the MMR initiation. In routine practice, contouring and dosimetry files were reviewed by 66% and 83% of centers practicing MMR, respectively. However, only 40% enrolled the data in a registry dedicated to the surveillance. Finally, 78% expressed interest in initiating a consensual procedure.

Conclusion

MMRs are not systematically implemented in the worldwide RT departments. In xxxxxx and Europe, few departments with quality assurance programs have implemented MMRs. This survey showed that a large majority of the centers are interested in implementing an MMR with a formalized procedure. Our project could help to increase interest of the worldwide RT community in this topic.

Keywords: cancer; radiotherapy; survey; organization; morbidity review; toxicity

Introduction

Increasing international interest has recently arisen in using morbidity and mortality rates to monitor the quality of hospital care (1,2). Many hospitals have integrated morbidity and mortality review (MMR) meetings into their governance processes by making them mandatory and more accountable for taking corrective actions (3-5).

The quality of radiotherapy (RT) delivery is highly operator-dependent. It relies on a dedicated team of professionals involved in a complex, multi-step process with a margin for errors that could affect outcomes and toxicities. Some deviations may have minimal effects on outcome while others may have a profound impact and may compromise long-term results. In addition, an accumulation of minimal deviations may also have dramatic consequences in the end. For more than 10 years, the development of quality assurance programs, including implementation of feedback committees (FBC) dedicated to the registration, analysis and correction of precursor events, has been mandatory in xxxxx centers. Beside FBC, the National Cancer Institute has advocated going further on the shifts and the registration and management of late toxicities through the PROUST project in order to formalize a MMR procedure and omit the confusion between FBC and non formal MMR.

Concerning RT morbidities, MMR is identified as one of the most adapted processes to highlight whether and how these meetings provide assurance within the organizations' governance processes of RT departments. Systemic analysis conducted during the MMR is a comprehensive analysis of the situation, taking into account all technical and human elements. In a recent report, we described a single institution's experience using a dedicated MMR procedure associated to one individual radiosensitivity test in selected patients (6). This pilot study allowed understandable answers that professionals can offer to patients suffering from severe toxicities. It also tried to understand the potential relationships between clinical events and individual radiosensitivity in a multiparametric and complex context. In addition, we

showed that our research program may contribute to educating our staff to monitor radiation-induced toxicities, recommending introduction of the MMR procedure in RT departments.

In xxxxxxxx, implementation of MMR in RT departments is very heterogeneous and does not always meet the criteria defined by the Health Authorities (HAS) for other specialties (7). In addition, a formalized procedure is not yet mandatory for systematic MMR, implicating major efforts by professionals who are convinced of the real impact and necessity to achieve better healthcare.

The PROUST (Prospective Registration of morbidity and mortality, individual radioSensitivity and radiation Technique) project is constructed to define the best way to disseminate MMRs in the centers according to a formalized procedure completed after several steps. The first step consisted of: (i) drawing an inventory of the existing MMR procedures in RT departments in xxxxxxxx; (ii) defining the optimal MMR procedure with standardized criteria for practical organization before inclusion of patients in the PROUST registry with clinical, physical and biological characteristics (Convention Plan Cancer-N° HAP2016-01). We present herein the results of the PROUST survey.

Materials and Methods

Survey questionnaire and procedure

A web-questionnaire was sent to 351 radiation oncologists working in 172 centers. The objective was to reach the maximum number of radiation oncologists and to collect MMR practices in each department.

The questionnaire included at least three sections. The first section was dedicated to the organization and quality assurance meetings practice in the departments. The second section specifically focused on MMR meetings organization in terms of frequency, membership, governance and number of patients' files reviewed. The rest of the questionnaire aimed to detail the referent members for review, reasons for non-implementation of MMRs and asked

if departments were interested in initiating MMR meetings following a consensual national procedure (Table 1).

MMR procedure proposal

One of the main objectives of the project was to structure homogeneously the MMR meetings in the xxxxxxxx RT centers according to the same criteria. The clinical, dosimetric and biological characteristics will be recorded on a dedicated chart. Radiation oncologists from the participating centers who detect a severe and durable toxicity will register their patients in the MMR database. They will initiate discussion of all or the more complex cases in a scheduled forum. In such meetings, the cases will be presented, any imaging displayed, and the contoured volumes and dosimetry detailed. Where controversy may exist, comments may be noted and discussed regarding the observed toxicity and its potential relationship to radiotherapy parameters, such as fractionation used, target volume coverage, dose-limiting tissue close to target volumes, optimal dose and its distribution, organ at risk (OAR) constraints, and treatment positioning imaging accuracy during treatment.

Clinical data collection

Radiation oncologists will collect all the clinical data related to the patient, tumor details and applied treatments, including loco-regional and systemic therapies if they exist. The CTC v4.3 scale will be used for all toxicities.

Dosimetric data collection

The referent radiation oncologist and a senior physicist who will be nominated for each patient will perform a new evaluation of all steps of patients' care, including contouring, treatment planning and quality of treatment delivery. They will collect all relevant dosimetric data related to the target volume coverage and the OAR sparing. These data will be reported on the same flow chart and compared to the plan used to treat target volumes and dose constraints accepted to the OAR for the prescribed treatment.

Results

Participating centers

As of July 2017, we received 108 responses (63%) from the 172 centers, 107 of which were completely filled in. They included 65 private and 42 public institutions.

MMR procedure implementation

One hundred percent of the centers declared that they had initiated a Quality Assurance program in the department, including the development of a security policy following a validated procedure, for more than 10 years in xxxxx (8). The implementation of feedback committees (FBC) dedicated to the registration, analysis and correction of precursor events was reported by all centers. Conversely, less than half the centers (51/107; 47%) have implemented MMR procedures. However, among these 51 centers, only 47 reported the details on their MMR organization. In addition, there was significant confusion with FBC in the large majority of them. Indeed, only 10 of 47 centers (21%) declared that MMRs are organized systematically every six months. For the other centers, MMRs were either organized every three years (n=2), yearly (n=7), or only if needed for a given patient with abnormal toxicity (n=11). In the latter and in the other 17 of 47 centers (36%), no details were given for the delay and the fact that MMRs were mixed with FBC without a formal and distinct methodology.

MMR organization

The PROUST survey showed that the centers that had implemented MMRs were initiated by doctors (97%) for more than 2 years in 59% of the centers. The regularity of the MMR meetings organization was very heterogeneous, depending on the centers. Our survey showed that, in about a quarter of the centers (24%), MMRs were organized only when new files were presented or according to the number of files registered in a given period. The regular

organization of every six and 12 months was observed in 21% and 15% of the centers, respectively. Finally, less than four new files per MMR and 10 new files per year are discussed, respectively, in 83% and 70% of the centers. MMR duration is less than 60' and 90' in 60% and 34% of the centers, respectively.

In the majority of centers (60%), acute and late toxicities \geq grade 3 are the main reasons for a MMR procedure initiation. However, only 36% of the centers take photographs (for visible toxicities) at diagnosis and during follow-up of the toxicity. Finally, 26% of the centers performed at least once an available radiobiology assay in xxxxxx to evaluate patients' individual radiosensitivity. These tests are planned prospectively in the PROUST study (9,10).

MMR in routine practice

The PROUST survey showed that 55%, 27% and 20%, respectively, of the centers did not implement the MMR procedure because of lack of time, impossibility of bringing together professionals for meetings, and lack of toxicity justifying MMR, respectively.

On the other hand, the impact of the MMR on post-treatment surveillance was important. Earlier surveillance was undertaken in 79% of centers as a result of the MMR. From a practical point of view, contouring procedures (of the target volume and OAR) and dosimetry criteria were reviewed by 66% and 83% of the centers practicing MMR, respectively. However, only 40% of them enrolled the data in a registry dedicated to the surveillance.

The file review was done by a tandem of a physician and a physicist in all centers. The physician and the physicist who initially treated the clinical case were involved in the MMR review in 62% and 42% of the centers, respectively. A new physician and a new physicist not involved in the initial treatment planning were nominated for the MMR review in 33% and 47%, respectively.

Finally, among the centers that have not yet implemented MMR procedures, 78% were interested in initiating a consensual procedure and registering their patients with grade ≥ 3 toxicity in the Proust Database. The main results are presented in Table 2.

Discussion

Radiotherapy is considered as a very high-risk domain in different steps of the planning and treatment process. There is a potential margin for error in all these steps. Some deviations may have minimal effects on outcome, while others may compromise long-term results and the quality of life of our patients. It is important that the process of tumor/target assessment, OAR and constraints definition, treatment planning and treatment delivery follow acceptable standards to ensure optimal patient clinical benefit. Otherwise, insufficient tumor control (due to inadequate doses (or coverage) to the target) or unacceptable complications (due to excessive doses to normal tissues) are possible. The process of ensuring that goals are met is the core of quality assurance in RT and should be systematically present at a departmental level.

It is then essential to differentiate experience FBC and MMR meetings. In xxxxx, the development of a security policy started in 2003 with the help of xxxxxxxx Consulting. At that time, three anti-cancer centers worked together on the implementation of FBC meetings dedicated to the registration, analysis and correction of precursor events (8). Since that pilot program, the process of FBC has been generalized to all RT centers and has become a regulatory requirement in all departments under the control of the xxxxx xxxxxxxxxxxx (xxxxxxx).

For morbidity after RT, MMR meetings must be distinguished from FBC. The MMR procedure is clearly identified as one of the most adapted processes to highlight whether and

how the meetings could facilitate quality improvement, be accountable and provide assurance within the organizations' governance processes in RT departments.

However, in xxxxxx, many teams have not yet achieved the establishment of such a formalized procedure that focuses on morbidity and mortality systematic review. To our knowledge, the PROUST survey is the first MMR implementation practice survey reported for RT. We showed that only 47% of the xxxxxx departments have integrated MMRs in their quality assurance processes and organization governance, with significant confusion with FBC meetings which have been implemented in 100% of the centers.

MMR meetings already exist in many other medical specialties/healthcare organizations and provide a governance resource that is underutilized. They can improve accountability of morbidity and mortality data and support quality improvement without compromising professional learning, especially when facilitated by a standardized review process.

Recently, increasing international interest has arisen in using morbidity and mortality rates to monitor the quality of hospital care. Many hospitals have integrated MMR meetings into their governance processes by making them mandatory and more accountable for taking corrective action (11,12). To support this, the US Agency for Healthcare Research and Quality has produced web-based guidance for case analysis (13). However, guidelines for a given specialty cannot be applied to another as the processes are widely different. For example, in the surgery MMR process, adverse outcomes discussed at MMR meetings may be attributed to individual competence in treating patients rather than the system or process failures involved with the care (14,15). Although both contribute to errors, the focus on individuals has led clinicians to fear embarrassment and loss of reputation, making them reluctant to speak openly about errors at meetings. This defensive behavior is thought to be counterproductive to eliminating adverse events and assuring safe care. Higginson et al. (11) showed considerable variation in the way deaths were reviewed and a lack of integration of

these meetings into the hospital's governance framework. The introduction of the standardized mortality review process strengthened these processes.

In the PROUST survey, among the centers that have implemented MMR meetings, only 10 and 7 centers declared that they organize MMRs every 6 and 12 months, respectively. Overall, one-fourth organize MMRs only according to a diagnosis of late severe toxicity. The maximum number of MMR board meetings is 10 per year. The survey showed that <4 new cases per meeting and <10 new cases per year were discussed in 83% and 70% of the centers, respectively. Unfortunately, we could not collect the total number of cases discussed in each center since the start of MMR implementation.

MMR is defined as "a collective retrospective analysis, and systemic case marked by the occurrence of morbidity, complication, or event that could cause patient harm (adverse events) with the objective of the implementation and monitoring of actions to improve the care of patients and safety of care". Systemic analysis conducted during MMR meetings is a comprehensive analysis of the situation, taking into account all the elements (technical and human) involved with the patient care. Thus, it overcomes the single reflection centered on one or more individuals.

In the PROUST Survey, the reasons reported by centers that did not implement MMR were mainly related to lack of time to bring together all the professionals involved in the treatment steps (55%). However, 78% of the centers that have not initiated the MMR process are interested in implementing it following structured guidelines. For FBC, the fact that the procedure was supported by the health authorities made it legally mandatory and implemented in 100% of the centers for more than 10 years. Thus, we believe that the 3/4 of the centers who are interested in a formalized MMR procedure would disconnect it from the FBC and use these meetings to respond positively to the legal obligation of radiation-toxicity registration. Also, the fact that the Proust project offers the possibility of evaluating intrinsic

radiosensitivity of the patients is encouraging for a deeper explanation of the toxicity when all parameters of RT are respected. In our experience, the organization of MMR each 6 months is widely accepted without any opposition (6).

The diagnosis and type of morbidity depends on the irradiated volume, the dose delivered to the OAR and the individual radiosensitivity of the patients (6,16). Management of the radiation-induced morbidity depends on the severity of the toxicity and the involved organs. Thus, follow-up after radiation therapy is important to evaluate outcome results and late toxicity that generally consists of tissue fibrosis and vascular damage, which can result in cosmetic and functional deterioration. The challenge of clinicians in the frame of the MMR is to ensure that there is no controversy about the quality of the delivered radiotherapy and to investigate other potential causes, such as the particular individual radiosensitivity of the patient for a given standard treatment. In the PROUST survey, there was significant impact on the behavior of the teams on patient follow-up. Significant awareness is noted with a shortening of the delay between surveillance visits in 79% of centers that have implemented MMR meetings. However, in xxxxxx and xxxxxx, many teams have not reached a formalized procedure for a systematic MMR or still continue to confuse between MMR and FBC processes. In addition, as shown by the PROUST survey, implementation of MMR in radiotherapy departments is very heterogeneous and does not always meet the criteria defined by the Health Authorities (HAS) (7). The Henri Mondor MMR procedure reported recently (6) included specific screening of patients in a dedicated visit followed by an exhaustive review. This methodology could serve as a basis for thinking about the specifications of “an ideal MMR meeting procedure” to be implemented in the xxxxxxxx and worldwide RT departments.

Conclusions

MMR meetings exist in many healthcare organizations and are a governance resource that is generally underused. A standardized MMR meeting procedure in RT departments is still lacking. The PROUST survey showed confusion between MMR and FBC meetings among xxxxxxxx RT centers. The majority of centers that have not implemented MMRs declared their interest in a formalized MMR procedure. Regarding the rest of the world, there is no clear report on MMR procedure. Thus, we believe that this is a great topic to study and the PROUST project could be the «wake-up call» for many radiation departments regarding MMR implementation.

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Table 1. PROUST Survey questionnaire sections description for MMR meetings practice

Section 1	Section 2	Section 3
QA program implantation availability in the department	MMR organization	MMR practice
<i>Centers, Teams and QA Organization</i>	<i>MMR Organization</i>	<i>Practice of Patient/file Reviews</i>
Organization & QA meetings	Specific MMR meetings organization	Referent member missions
Centers description	Time since start of MMRs	Clinical toxicity registration
Meetings: <i>MTD board meetings</i>	MMR board members' description	Dosimetry review
<i>CERx</i>	Frequency of MMRs/year	
<i>MMR</i>	Number of patients/files discussed/MMR: <i>New files (patients) vs Updates (previous declared patients)</i>	Photographs of toxicity in routine
	Selection criteria of patients' inclusion	
	Mean time duration of MMR	
Time since start/ Team expertise	Professional present during meetings	
	Non implantation of MMR: <i>Reasons for non implementation & Interest to participate to prospective project</i>	

 QA: quality assurance; MTD: multidisciplinary board meetings, CERx: feedback committees dedicated to the registration, analysis and correction of precursor events; MMR: Morbi-mortality review meetings;

Table 2. Results of the survey on MMR practice and organization

Survey questions	% of responses (n=107)
CREx organization	100 %
MMR organization (n=47)	47 %
MMR initiation in the department	
- Radiation Oncologist	82 %
- Physicist	15 %
- Others	3 %
Timing	
- Every 6 months	22 %
- Every year	15 %
- According to the number of cases	22 %
- Unknown	41 %
Number of new patients discussed per year	
- < 10	70%
- 10-20	19%
- > 20	4%
	7%
MMR duration (minutes)	
- 30	6%
- 60	60%
- 90-120	34%
Number of patients discussed per MMR	
- < 4	83%
- 4-8	4%
- > 8	4%
- Others	9%
Reason for file presentation	
- Acute or late toxicity $G \geq 3$	60 %

- Acute or late toxicity $G \geq 2$	15 %
- Other	25 %
Reviews:	
- Dosimetry review	82 %
- Data registration in a local database	40 %
- Photography systematic practice	55%
- Intrinsic radiosensitivity tests practice	25 %
Interest to participate to a prospective MMR project	78 %

CRex: feedbacks committee dedicated to the registration, analysis and correction of precursor events; MMR: Morbi-mortality review meetings; QA: quality assurance;