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ORIGINAL ARTICLE

"Distributed proton radiation therapy"-A new concept for advanced competence support

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Abstract

The increased interest in high precision radiation therapy is to a large extent driven by the potential of modern imaging technology. The aim of this project was to analyse how an expensive proton facility best could support a multi-centre health care system. We have developed a model for distributed expert collaboration where all clinical experts will work close to their patients in regional centres. Patients who are candidates for proton therapy will be examined and dose-planned at their regional clinic, discussed in a fully information supported video conference and digitally made available at the proton treatment facility. The proton facility itself will be placed near a communication centre easily reached by all patients where they will be treated under full responsibility of their own physician at the home clinic. This concept has been analysed in detail both with respect to the overall functionality and with respect to possible weaknesses. It was found that the concept of distributed radiation therapy, as proposed here, will offer a stable clinical solution for advanced radiation therapy. It will support the spread of knowledge, serve as a fully developed backup system and the concept will further serve as an efficient base for clinical research.

The special characteristics of traditional low-LET radiation therapy, mainly delivered by photon or electron beams, have proven successful for more than a century. This type of radiation has, contrary to surgery, the potential of sparing normal tissue functions also when the tumour infiltrates these tissues. As in all types of radiation therapy, however, risks for significant side effects are present, especially in treatments with a curative intent, where high doses are delivered in order to eradicate the tumour. This means that precision, both in the geometrical extension of the irradiated volume and the actual dose delivered to the tumour region, are very critical. Modern technologies in imaging, such as CT, MR and PET, will allow for a more detailed and accurate delineation of the tumour and the surrounding healthy tissues, of which the organs at risk are of special importance. The gradual introduction of these technologies for tumour characterisation has also led us to increase the conformity of radiation therapy from 2-D representation of the tumour volume to 3-D conformal radiation therapy, based on CT imaging. Recently, computer controlled radiation therapy delivered by intensity modulated photon beams, IMRT, has become a standard in many clinics. This gradually increased precision of radiation therapy enables the delivery of a higher tumour dose often with fewer or less severe side effects. The next step in this development, as pointed out in e.g. the Swedish Cancer Society Radiation Therapy Research Investigation [1] and by the Swedish Council on Technology Assessment in Health Care (SBU) [2] will be to further develop advanced functional imaging for a more individualised characterisation of the tumour. The radiation targets determined using these methods will be even more specific implying further increased demands on high precision radiation therapy. Proton therapy

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as part of the radiation therapy arsenal is already justified [3] and with respect to the ongoing development in the field, the future need for high precision therapies will be even more pronounced. Availability of such high precision therapies will stimulate future research and clinical implementation of these more advanced imaging techniques. Until today a number of research institutes have been treating patients with protons for a rather long period but many of these facilities are experimental sites with severe technical limitations, often in combination with a limited patient capacity. However, recent developments in the beam handling systems have significantly enhanced the clinical interest and the commercial development of proton therapy. These systems consist of a high energy particle accelerator, a very advanced beam transport system and a large gantry construction, which means that such systems will still be expensive and require advanced expert support.

The number of Swedish patients that at present potentially would benefit from proton therapy has been estimated to approximately 2 200 per year for the Swedish population of 9 million inhabitants [4]. Similar estimates have also been made in other European investigations [5]. This figure constitutes approximately 15% of all irradiated patients but it varies substantially between tumour types [6–13]. A further conclusion from these studies was that approximately 50% of these patients should actually be treated solely with protons, if this was a realistic option today, while the rest were expected to be treated with protons in combination with conventional radiation therapy. In the investigation performed in Sweden, the number of treatment fractions per patient would on average be 15 [14]. It was further assumed that half of these patients would for different reasons be treated in the home clinic anyway. The total proton capacity needed for the Swedish population would thus be approximately 15 000 fractions per year.

Currently, most proton therapy centres are organised with equipment and the whole staff of experts at one single site. All patients will thus be referred to the centre, mainly by physicians who themselves are not always familiar with the actual characteristics of proton therapy. Modern information technology does, however, offer much more appealing solutions to this problem. Radiation therapy of today can be divided into a planning and a prescription phase completely separated from the therapy delivery procedure itself. This is in general analogous to the separation between prescription and delivery of drugs in regular health care. To guarantee a high health care quality for all individual patients, access to colleagues with expert knowledge in the field is, however, critical. A distributed solution with expert colleagues on-line should have the potential to secure quality in this respect. This type of distributed collaboration with treatment planning conferences as an integrated part of the process has in theory been described to be very efficient to remotely support smaller radiation therapy clinics which is accordance with the practical experience from the northern part of Sweden and the collaboration between Umeå and Sundsvall [15–17]. It is also believed that the network formation will help to obtain and maintain a high level of competence on all of the involved centres.

There are many potential advantages with such a distributed concept for an advanced radiation therapy like proton therapy. Most important is probably that the expert knowledge of how to best use protons will be a natural part of all participating clinics and thus always available near the patient. It is further important that all proton plans are compared to those for other radiation therapy modalities in order to validate the actual gain on an individual basis before the limited capacity of an advanced proton facility is used. Finally, the whole process should be significantly less vulnerable when experts from any clinic can be called in with very short notice to support other clinics or the proton therapy site over the network.

An advanced proton facility should already from the beginning be designed to host research projects including clinical trials and clinically orientated experiments focused on development of new technologies and methods in radiation therapy and dosimetry. The advanced tools in a distributed network solution will be essential parts in supporting a nationwide scientific collaboration. An in depth analysis of the clinical demand, organisation, equipment and research for a common proton therapy facility was performed by a group of oncologists and medical physicists appointed by all ten university clinics in Sweden together with invited representatives from Norway and Denmark [14]. The present study is focused on designing and analysing a model for distributed competence support of a centrally located proton therapy unit for intensity modulated proton therapy. The basic requirements and assumptions used in the development of the concept have mainly been based on clinical requirements presented by Glimelius et al. [4] and existing technologies on the market. Details in the process have been analysed in order to highlight weak points possible for improvements. Specific advantages and possible disadvantages have also been analysed.

Basic conditions and methods

In order to develop clinical routines and determine the technical details in a centre for proton radiation therapy based on the concept of distributed competence, a number of basic requirements and assumptions have been identified. These parameters have been determined for the clinical requirements present in Sweden with a population of 9 million inhabitants distributed over an area of 450 000 km^2. The Centre is supposed to be organised in one central proton treatment node and about ten collaborating university or other major clinics (home clinics). The central node should be a pure treatment facility which means that patients cannot be referred directly to the proton facility for treatment; instead all patients must be prepared for the proton therapy at a home clinic. A core concept will be the distributed radiation oncology and medical physics competence within all participating hospitals supported by cutting-edge information technology and telemedicine technology. All planning information should be handled over a secured high capacity computer network. The intention is further that the travelling time for the patients should be restricted to less than 3 h from the home clinic.

Basic considerations and requirements

1. The referred patients will come from up to ten collaborating clinics.
2. Externally referred patients will be handled under full clinical responsibility of a collaborating home clinic.
3. Patients will remain under full medical responsibility of the home clinic during and after the proton therapy course. There must be full competence at site, however, for taking care of any acute problems arising during the course of therapy.
4. The proton therapy node in the Centre should be a dedicated medical proton therapy facility.
5. The Centre will initially be designed for 15 000 treatment fractions per year and it will be prepared for future expansion.
6. The treatment facility will be equipped with intensity modulated proton therapy (IMPT).
7. The treatment node will be geographically located near a national communication centre.
8. The majority of the patient treatments should be part of prospective clinical studies and thus treated according to approved clinical protocols.
9. The Centre will be organized internally and logistically from a strict patient-orientated perspective.
10. The *ISO 9001:2000 Quality management system* should be implemented.

Basic assumptions

A core concept for the Centre will be to utilize distributed radiation oncology and medical physics competence within all participating hospitals using cutting-edge information technology and telemedicine.

1. The Centre will be financed and administrated under shared governance of the collaborating clinics.
2. All patients will be fully examined and planned at their home clinic.
3. Combined treatments will be planned and performed at the home clinic, except for concomitant medical treatments requiring e.g. intravenous or other injections.
4. All patients will be discussed in regular distributed teleconferences before proton therapy is prescribed.
5. Proton beams are delivered at the treatment site and patients will be observed with respect to acute toxicity.
6. Patient follow-up will be handled by the home clinic and registered in a central data base.
7. Clinical availability with verified proton beam quality should be guaranteed to at least 95%, i.e. similar to conventional radiation therapy.
8. The possibility to extend the facility in a long-term perspective to include also treatment with heavier ions should be considered.

Results

A model for a national proton therapy centre for distributed expert collaboration has been developed. This solution is based on the requirements specifically determined for this type of highly specialised clinical activities. One main issue was to serve all patients, independent of their place of residence, with the same access to high quality and highly specialised health care. Another issue was to optimise the use of invested resources and secure long-term availability of experts and further development over time.

Overall logistics

All preparations before radiation treatment, e.g. diagnostic and planning procedures, will take place at the home clinic in close contact with the patient. When a treatment prescription has been discussed and approved in a common video-based conference,

the patient will travel to the Centre and the prescription will instantly be available on the network server for treatment.

The overall logistics is described in more detail in Figure 1 where also a time line, the location of the activities involved and the patient location during the whole process are illustrated. In this example the number of treatment fractions has been set to 15 which actually could vary significantly between patients. Another parameter that also may vary for different treatments is the number of fractions per week.

The patient fixation used must be well documented by a set of specified parameters and/or images. As the fixation device is individually made and adapted at the home clinic it will have to be transported to the proton facility together with the patient.

The treatment optimisation should be performed on a treatment planning system where the proton plan can be compared with plans made for locally available treatment units in order to decide, on an individual basis, if the patient would significantly benefit from having proton treatment, either as the only radiation treatment or as a part of a treatment with mixed proton and conventional radiation therapy delivered in the home clinic. Alternatively, the patient may be asked to participate in a clinical trial where the aim is to improve knowledge about the value of proton therapy.

Before any treatment plan is approved for therapy it must be discussed in a common network based conference with participants from all the collaborating clinics. This conference is scheduled to 40 min twice a week with approximately ten patients in each conference. All patient related information will be available on the common network and thus simultaneously viewed in all clinics at the time of the conference. The infrastructure of the information technology (Figure 2) is based on a secured hospital network connecting all sites, a central server where each hospital can upload patient related information, images and treatment plans, etc. In the same system patient treatment data generated during the proton therapy will be stored and is thus fully updated. This information about the progress of the patient treatment will always be available in all home clinics. In parallel with the database a multi-part video conferencing system and a multi-part application sharing software will be available in order to facilitate smooth conferencing activities. A common booking system and treatment planning software supporting both the proton facility as well as the local therapy facilities will also be part of the network based infrastructure.

Approximately 80% of the patients in Sweden will have to stay in a hotel near the treatment facility during their course of treatment. For good patient care and flexibility (in case of shorter technical

Time/day	Activity	Activity location		Patient location			
		Home clinic	Proton site	Home clinic	Home	Hotel	Proton site
0	Referral						
1	Fixation	■		■			
2	CT, MR or PET for treatment planning Treatment optimisation	■		■			
3	Planning conference, plan approval Transfer of data	■	■		■		
4	Transportation of patient + fixation Patient related QA, without patient		■			■	
5	Continued patient related QA, with patient Treatment 1		■				■
6	Treatment 2		■			■	■
7	Treatment 3		■			■	■
8	Treatment 4		■			■	■
9	Treatment 5 and Patient round	■	■			■	■
10	Rest				■		
11	Rest				■		
12	Treatment 6		■			■	■
13	Treatment 7		■			■	■
14	Treatment 8		■			■	■
15	Treatment 9		■			■	■
16	Treatment 10 and Patient round	■	■			■	■
17	Rest						
18	Rest						
19	Treatment 11		■			■	■
20	Treatment 12		■			■	■
21	Treatment 13		■			■	■
22	Treatment 14		■			■	■
23	Treatment 15 and Patient round	■	■			■	■

Figure 1. A time-line illustration of the overall procedure in distributed proton radiation therapy.

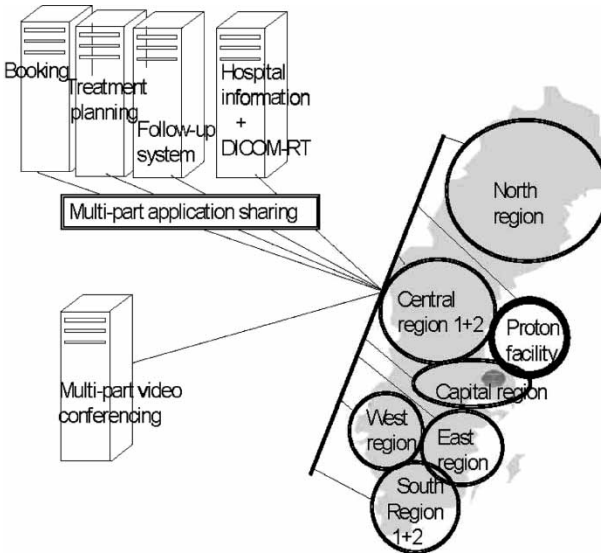

Figure 2. An illustration of the information technology concept. Eight regional centres and the proton site are connected through a secured high-capacity network. A number of applications including an information server are also connected to this network. All applications can be used individually by any node on the network or viewed simultaneously by use of an application sharing software. This collaboration software is supported by a video conferencing system on the same network.

problems) the hotel must be placed in direct connection to the treatment site. The hotel must be dimensioned with respect to the number of patients treated per day. In the present planning it is estimated that 80% of the patients will stay in the hotel (six patients per hour during 8 h). This means that a room capacity of 40 patients will be needed. Some of the rooms must be large enough to host relatives or families and part of the hotel environment must be prepared with respect to paediatric patients.

Two main issues have been analysed regarding the localisation of the proton facility. A majority of the patients will have to travel by bus, train or air which means that the treatment node should be localised near a communication centre readily accessible from all collaborating clinics. The planning goal is a maximum travelling time of 3 h from the home clinic. For Sweden this will point out the Arlanda airport region as the most suitable location. Another important perspective which must be included in the localisation planning is the access to advanced medical care.

Logistics in the therapy facility

A suggested workflow aiming at a production of 15 000 fractions per year is illustrated in Figure 3. The example is based on two proton gantries with full 3-D pencil beam scanning and a spare room with a fixed beam. All patient set-up and fixation will be performed in four separate preparation rooms equipped with advanced position verification devices. For soft tissue verification MR will be the best choice while CT can be used for bony landmark verification and optical devices for patient surface verification.

In the example presented in Figure 3 the total time of delivery of all beams in each fraction was set to 7 min with a room switching time of 2 min. According to this rather conservative model the beam time seems to be the limiting factor. The time per patient in the treatment room includes both repositioning and a fast verification before the actual irradiation. This time was set to 11 min but could be significantly extended without interfering with the overall process. The patient time in the preparation room is not critical and may fluctuate without interfering with other activities. The average total time per patient in the process will then be 37 min but may be allowed to vary significantly depending on the individual patient.

The example in Figure 3, which is based on four preparation rooms and two treatment rooms, will produce six full treatment fractions per hour. Assuming 8 working hours per day, 7 days per week and 48 weeks per year would sum up to 16 128 fractions per year. This is just a few percent more than the planning goal of 15 000 fractions per year.

In a distributed health care model of this type where the therapy prescription has been decided in the local hospital and the therapy should be delivered according to this prescription at a remote site, the overall organisation of a patient related quality assurance system is very important. Some of the most critical parameters to verify by such a QA-system are the data sent to the therapy facility, the patient set-up procedure, the patient related dosimetry, follow-up of the treatment prescription and possible modifications during the course of therapy. All QA-procedures, both equipment related and patient related should follow the *ISO 9001:2000 Quality management system*.

Discussion

The overall goal of this concept was to add the proton functionality to the arsenal of existing conventional radiation therapy beams available in all major clinics today. Protons should thus be one of the basic modalities available for all treatment planning in the clinics. However, proton therapy equipment is expensive and needs special expert support. We therefore suggest building one common site serving at least 9 million inhabitants, the population of Sweden. This facility will be supported

Time/min	Beam	G1	G2	Prep1_G1	Prep2_G1	Prep1_G2	Prep2_G2
0	Treat G1	treat		**Pat enter**		dress	
1				undress		talk	
2							
3				fixation		exit	
4						document	
5				laser set-up			
6							
7				CT/MR/opt		prepare next	To treat
8	Prepare G2	stop treat	Pat enter	.-localisation			
9			verify setup		Back		
10	Treat G2		treat		dress	**Pat enter**	
11					talk	undress	
12							
13					exit	fixation	
14					document		
15						laser set-up	
16							
17				To treat	prepare next	CT/MR/opt	
18	Prepare G1	Pat enter	stop treat			.-localisation	
19		verify setup					Back
20	Treat G1	treat			**Pat enter**		dress
21					undress		talk
22							
23					fixation		exit
24							document
25					laser set-up		
26							
27					CT/MR	To treat	prepare next
28	Prepare G2	stop treat	Pat enter		.-localisation		
29			verify setup	Back			
30	Treat G2		treat	dress			**Pat enter**
31				talk			undress
32							
33				exit			fixation
34				document			
35							laser set-up
36							
37				prepare next	To treat		CT/MR
38	Prepare G1	Pat enter	stop treat				.-localisation
39		verify setup				Back	
40	Treat G1	treat		**Pat enter**		dress	
41				undress		talk	
42							
43				fixation		exit	
44						document	
45				laser set-up			
46							
47				CT/MR		prepare next	To treat
48	Prepare G2	stop treat	Pat enter	.-localisation			
49			verify setup		Back		
50	Treat G2		treat		dress	**Pat enter**	
51					talk	undress	
52							
53					exit	fixation	
54					document		
55						laser set-up	
56							
57				To treat	prepare next	CT/MR/opt	

Figure 3. Illustration of a tentative proton treatment process. The column "Beam" represents the available beam time, "G1", "G2" represent gantry room 1 and 2, "Prep1_G1" represents preparation room 1 for gantry room 1, etc.

by experts from the whole country by extensive use of modern information technology.

One central part of this concept is the efficient use of tele-conferencing where all patient data have to be available for all participants and simultaneously demonstrated. Present routines presented in the literature [15,17] are in general restricted by the number of participants. Today these restrictions are however not governed by technical limitations and further developments are to be expected in the near future in this important field.

Treatment optimisation should not be restricted to protons only. For optimal use of a distributed proton Centre all treatment planning and dose optimisation should be performed in an environment where all types of beams can be combined and optimised concurrently. A treatment planning system of this type must also be able to generate all parameters in

the setup for both the conventional therapy units and the proton facility. This type of tools for multibeam optimisations is not presently available even though most of the functionality in such a system is actually available in separate systems. Further development on mixed beam treatment optimisation is thus needed.

A subset of patient related hospital information data and images should be available for all clinics on a central server when the planned patients are discussed. Treatment related data will then be added subsequently during the therapy process. In order to handle the upload and download of data between the central information system and the local systems, further development of standardised interfacing will be needed. Efficient high precision methods for patient positioning will be used in the separate preparation rooms in order to allow for careful position verification without occupation of the treatment rooms. The different steps in this procedure must, however, be further analysed. As all initial patient positioning and fixation will be performed in the home clinic a very critical issue is to repeat the procedure with adequate precision at the proton site. For this purpose present fixation methods used in the different clinics must be further developed with respect to standardisation and documentation.

The capacity of the facility suggested here was optimised to the requirement of producing 15 000 fractions per year. This volume could in principal be obtained with only one gantry (Figure 3) but in order to maintain high quality and guaranteed up-time in the overall process a two gantry installation is suggested. In addition some backup capacity must always be available as the onset of treatment will in many tumours trigger a tumour cell re-population process where any unplanned gap in the dose delivery may reduce the intended effect of the therapy. Machine and patient related QA may also be time consuming activities. For these reasons there must be some spare capacity to be used when unplanned downtime occurs. However, if the actual beam delivery time and beam switching time can be shortened, the patient throughput suggested in Figure 3 can be significantly increased. Implementing extended working hours will of course also significantly increase the capacity, however at the cost of smaller margins for compensation of unplanned downtime. Other published models indicate similar production data [18].

In a sensitivity analysis, the minimum up-time of the proton treatment equipment has been specified to 95%. By this specification a downtime of at least one day per month must be covered by a security margin as patients who started treatment must always be treated to the prescribed dose at the average dose rate according to the prescription. Except for the accelerator system this distributed concept is in many essential parts dependent on a secured high-capacity network with global servers and shared applications. The expected down-time in any of these computerised systems has been regarded as negligible in comparison to the accelerator related safety margin already included in the model.

Vulnerability due to lack of expert competence will significantly be reduced in this distributed concept as temporary lack of experts in one site easily can be compensated by using experts in other clinics as all data can be accessed from all collaborating hospitals. The model will further improve the continuing education and research by the frequent video-based meetings between all experts in the field.

There are no firm demands stipulated on the participating clinics but we believe that a practical solution would be to use regional centres as nodes in this distributed network. Direct referral of patients to the proton facility will not be possible so all externally referred patients must be referred to one of these participating clinics. Each of these nodes would then be responsible for a population of one to two million inhabitants. There are, however, a number of basic demands which these clinics need to fulfill. Most importantly, all clinics must over time be prepared to maintain expert competence and participate in further development in the field of advanced radiation therapy, including proton therapy. The clinic must further participate in the scheduled tele-medicine conferences, locally implement common QC/QA-procedures and for periods of time send physicians, physicists and nurses to the proton facility as part of a staff exchange program. The distributed model will be a firm base for efficient clinical research as virtually all cancer patients will be known to the participating clinicians. This will guarantee an efficient inclusion of patients in e.g. clinical radiotherapy studies. This type of research is very important for treatments where evidence has not yet been shown as the use of expensive and advanced therapies must be directed towards those patients who will really benefit from it. The Swedish health care system is an ideal environment to perform this type of randomised studies as the inclusion of patients will be based purely on scientific considerations without being affected by other factors.

Conclusions

Distributed radiation therapy will be an efficient tool where highly specialised proton therapy can be made available on equal conditions to a whole population. In this concept all patients will be under the care of

up to ten collaborating therapy centres and all clinical experts will be located in these centres. A powerful set of information technology tools will connect these centres in real time over a secured high-speed computer network. This group of experts will guarantee high and stable quality in the clinical process and will further be an excellent basis for research and continuing education. Both for clinical support and educational purposes some positions for physicians, physicists and nurses will be staffed on a rotation schedule by visiting personnel from the collaborating clinics.

The proton therapy facility itself will be located near a public communication centre and will be supported by an integrated hotel offering a convenient atmosphere for the patients staying there during the course of therapy.

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