

Arteriography of the lower leg : a comparative study between conventional arteriography and intraarterial digital subtraction arteriography

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13. SUMMARY

A clinical study on the interpretability, consistency, graftability, radiation exposure and costs of conventional arteriography and intra-arterial digital subtraction angiography in the diagnosis of arterial occlusive disease in lower leg arteries is described. It was performed in patients who were candidates for a vascular operation, after prior clinical and non-invasive diagnostic tests had been performed.

CHAPTER 1

The aim of the study described in this thesis was fivefold:

1. to compare the interpretability of CA with IADSA of lower leg arteries;
2. to compare the consistency of readings of conventional arteriograms with those of intraarterial digital subtraction arteriograms of lower leg arteries;
3. to compare the assessment of graftability on the basis of CA and IADSA of lower leg arteries, and, retrospectively, after the operation has been performed;
4. to compare the the radiation doses for CA and IADSA of the lower extremities;
5. to compare costs of CA and IADSA of the lower extremities.

CHAPTER 2

General aspects of arterial occlusive disease are outlined in this chapter. It includes the etiology, pathology and significance of a hemodynamic critical stenosis with the development of collateral circulation. A description is given of the Fontaine classification, used in the clinical grading of arterial obstructive disease. The chapter also pays special attention to the therapeutic aspects, surgical as well as radiological. The problems encountered with arteriography of the lower leg are briefly noted. A review of the normal and variant anatomy of knee and lower leg region is given.

CHAPTER 3

A review of current non-invasive diagnostic methods used in the assessment of arterial disease is given, including a short note on the value of direct intra-arterial pressure recording.

CHAPTER 4

This chapter deals with the history of conventional arteriography in general, and more specifically with the development of arteriography of the extremities. Techniques of arterial puncture, methods of contrast injection and filming techniques are described. A review is given of the different complications which may occur during or after arteriography. The use of intraoperative arteriography as an extra diagnostic tool is discussed. In this chapter special attention is paid to the pitfalls which can influence the correct interpretation of films.

CHAPTER 5

This chapter describes the discovery of photographic subtraction by Ziedses des Plantes and reviews the literature on all aspects of DSA. The four different types of electronic (digital) subtraction are explained, viz., first order subtraction in time, energy, or depth, and second order subtraction using a combination of parameters. A brief overview is given of the technical aspects of DSA and a description of the components which are combined to form a DSA system.

The importance of spatial and contrast resolution in relation to the images formed by CA and DSA is explained in this chapter. The possibilities of image manipulation using DSA are discussed, as well as the possibility of studying circulatory dynamics (parametric imaging).

Present methods of image display are also described, including matrix camera and laser imager recording, and a view is given of the methods of image storage with digital optical disks.

The introduction of intravenous DSA and the shortcomings of this technique discovered later are described here, as well as the subsequent application of intraarterial DSA in general, and its specific application to intervention, trauma and tumors. The development of intraoperative DSA and outpatient DSA is also described.

CHAPTER 6

This chapter reviews results from the literature which advocate an aggressive approach for limb salvage therapy instead of limb amputation. This necessitates a reliable method to obtain preoperative diagnostic information on the status of the vascular tree. IADSA is introduced as a new method with supposed extra diagnostic qualities as compared to CA. Comparative studies of CA and DSA in general and specifically related to the lower extremities are discussed. Advantages of IADSA over CA recorded in the literature are listed here.

CHAPTER 7

The patient population which entered the consistency study, the noninvasive tests and the use of the ankle-brachial index as a measure of grading the severity of arterial disease are explained in this chapter. Specifications of diag-

nostic imaging equipment for CA and DSA, the method of arteriography and subsequent method of film interpretation are described. The arteriograms which were eventually included in this study and the principles of the Kappa statistical analyses of data obtained are also described.

The patient population which entered this study was 145, but after preview, the arteriograms of only 100 patients were found to be eligible for an independent, blinded reading by four observers.

This group of 100 patients varied in age from 37 to 91 years, and consisted of 54 males and 46 females. More than 90% of the patients were older than 50.

Film interpretation was performed by four observers three to six months after angiography in two phases. In phase one all observers had to score on a data form whether the film was judged interpretable or non-interpretable. If the film was judged interpretable, a multicategorical stenosis grading (Angioscore) of the popliteal, posterior tibial, anterior tibial and peroneal arteries, and the presence of collaterals had to be marked.

In phase two, the above interpretation was extended by an assessment of the quality of the film by all four observers. If the film was judged non-interpretable, the observer had to score whether this was caused by low contrast, bone superposition or other factors. In this phase, the two observers who were vascular surgeons also assessed whether a vessel was considered amenable to grafting.

The chapter ends with an example of the Kappa statistical analysis used to measure the degree of interobserver agreement.

CHAPTER 8

100 patients had arteriograms suitable for observer interpretation. Because some patients had undergone examination of two legs simultaneously by TLA or Seldinger catheterization, each leg was considered as a separate arteriogram, resulting in 135 arteriograms for interpretation. Five major parts can be distinguished in this chapter, containing the results of this study.

In the first part the values of the ankle-brachial index (ABI) are shown, in relation to the total number of arteriograms interpreted and in relation to the non-interpretable arteries, separately for CA and IADSA.

The second part discusses the interpretability of the popliteal, posterior tibial, anterior tibial, and peroneal arteries in relation to the number of observers who considered an artery non-interpretable with CA or with IADSA.

The third and most important part shows the interobserver agreement, expressed as Kappa or weighted Kappa values, in interpreting a multicategorical Angioscore, 50% stenosis or occlusion in the total study group of arteriograms and the needle puncture group of arteriograms.

The fourth part attempts an assessment of film quality. A major cause of non-interpretable films in CA seems to be low contrast of the blood vessel, followed by bone superposition.

In surgical practice, the graftability of a vessel is partly attributed to the interpretation of the film. The last and fifth part discusses the difference between CA and IADSA when two vascular surgeons judge whether a vessel is considered amenable to grafting, on the basis of film interpretation alone, without prior knowledge of clinical information or results of non-invasive tests. A retrospective comparison is made with the actual operation performed.

CHAPTER 9

This chapter contains a summarizing discussion of the final results of interpretability, consistency and graftability. Special attention is also paid to the reason for non-interpretability of examinations. The use of Kappa statistics in the assessment of consistency of various other radiodiagnostic procedures, other than angiography, is highlighted.

CHAPTER 10

Dose measurements were carried out on patients undergoing aorto-iliac and lower extremity arteriography. Evaluation of the entrance dose to skin showed a higher value for IADSA in comparison with CA. A significant amount of emitted energy was found to be absorbed by the abdomen and pelvis.

CHAPTER 11

A comparative study was made of certain costs which could differ between CA and IADSA. In this chapter results show that specified costs are two times higher for IADSA than for CA, mainly as a result of equipment costs. The only savings occurred in film costs.

CHAPTER 12

The conclusions of this study regarding angiography of the lower leg are:

- After a first bolus injection of contrast medium, a significantly higher number of lower leg arteries are visualized by IADSA than by CA. Non-interpretable examinations with CA after a single bolus injection are often caused by low contrast of the artery or by bone superposition.
- The consistency of film interpretation for arterial obstruction is high for CA as well as IADSA in comparison with the literature, with a slightly better result for IADSA. Vasodilation by circulating contrast medium does not influence the consistency of film interpretation.
- more lower leg arteries are judged amenable to grafting on the basis of film interpretation with IADSA than with CA.

This may decrease the primary amputation rate in obstructive arterial disease by indicating the possibility of a femorocrural bypass. A successful femorocrural bypass instead of a leg amputation can save the high costs of a leg prosthesis followed by rehabilitation, and can improve the quality of life for the patient.

- The use of IADSA does not result in lower radiation exposure but in fact causes a greater entrance dose to the skin of the leg in comparison with CA. A significant part of the emitted energy during lower extremity arteriography is absorbed in the abdomen and pelvis leading to a higher entrance dose for IADSA than for CA.
- Lower extremity arteriography by IADSA is more expensive than by CA, mainly due to equipment costs. The only savings occur in the use of film material.

A recommendation on how to perform aorto-iliac and lower extremity angiography with present apparatus is given.

SAMENVATTING

In dit proefschrift worden conventionele arteriografie (CA) en intraarteriële digitale subtractie angiografie (IADSA) van het onderbeen vergeleken voor wat betreft de beoordeelbaarheid van de verkregen beelden, de consistentie van de interpretatie met betrekking tot de mate van arteriële obstructie, de stralingsbelasting voor de patiënt en de kosten.

De concrete vraagstellingen worden in **hoofdstuk 1** beschreven evenals de aanleiding tot dit onderzoek. **Hoofdstuk 2** geeft informatie over de aetiologie, pathologie en therapie van haemodynamische kritische stenosen in de bloedvaten van het onderbeen. In **hoofdstuk 3 en 4** worden de momenteel beschikbare methoden van respectievelijk noninvasief en invasief vaatonderzoek beschreven. De techniek en mogelijkheden van subtracties en met name van de digitale subtractie angiografie komen in **hoofdstuk 5** aan bod waarna in **hoofdstuk 6** de literatuur wat betreft de vergelijking van CA met DSA besproken wordt.

In **hoofdstuk 7** wordt beschreven hoe de patiënten voor het onderzoek werden geselecteerd en hoe het angiografisch onderzoek werd uitgevoerd en de beelden werden beoordeeld. Ook wordt hier de statistische analyse uitgelegd. In **hoofdstuk 8** worden de resultaten van dit deel van het onderzoek gepresenteerd waarna in **hoofdstuk 9** een discussie volgt.

Van de arteriogrammen (CA & IADSA) van 145 achtereenvolgende patiënten waren er 100 beschikbaar voor beoordeling op beoordeelbaarheid, de mate van arteriële obstructie (uitgedrukt in een Angioscore) en de aanwezigheid van collateralen. De onderbeens arteriën bleken met IADSA beduidend beter beoordeelbaar ($p < .05$) dan met CA. Dit verschil in beoordeelbaarheid was vooral groot bij de arteriën distaal van de trifurcatie.

Bij een subgroep van 52 patiënten werd bovendien onderzocht waarom in voorkomende gevallen de kwaliteit van de beelden als onvoldoende voor interpretatie beschouwd werd. Dit bleek meestal veroorzaakt te worden door een te gering contrastaanbod in het betreffende bloedvat en soms door hinderlijke botsuperpositie. CA werd om deze reden veel vaker als niet te beoordelen beschouwd dan IADSA. De interwaarnemervariatie (4 waarnemers) bij beoordeling van de mate van arteriële obstructie bleek slechts gering te zijn in

vergelijking met de gegevens uit de literatuur en was voor CA en IADSA vrijwel gelijk. Het grootste verschil in interwaarnemer variatie werd geconstateerd bij interpretatie van de CA en IADSA beelden van arteria tibialis anterior op occlusie. Alleen dit verschil was statistisch significant ($p < .005$). De interwaarnemervariatie bij de beoordeling van collateralen was beduidend groter en ook hier waren de beoordelingen van de CA en IADSA beelden ongeveer even consistent. Twee chirurgen beoordeelden zowel de CA als de IADSA beelden van 52 patiënten opnieuw maar nu op de mogelijkheid tot het aanleggen van een bypass. Hierbij bleek dat met behulp van IADSA beduidend vaker tot het aanleggen van een bypass besloten werd.

In **hoofdstuk 10** wordt beschreven hoe de stralingsbelasting (intreedosis [mGy]) bij zowel CA als bij IADSA wordt gemeten en wat de resultaat van die metingen is. Voor het onderzoek van het onderbeen blijkt IADSA altijd iets stralenbelastender dan CA. Het verschil is echter niet groot. De kosten van beide onderzoeken worden vergeleken in **hoofdstuk 11**. Ervan uitgaande dat beide onderzoeken evenveel tijd kosten, is IADSA ongeveer twee maal zo duur als CA. Dit verschil wordt vooral veroorzaakt door de afschrijvings- en onderhoudskosten. De daarbij gehanteerde bedragen zijn echter gebaseerd op het prijspeil (en prijsverschil) van eind jaren tachtig.

In **hoofdstuk 12** wordt geconcludeerd dat:

- na een eerste bolus-contrastinjectie meer arteriën van het onderbeen beoordeelbaar worden afgebeeld indien gebruik gemaakt wordt van IADSA dan wanneer gewerkt wordt met de conventionele arteriografie techniek.
- de interwaarnemer variaties bij beoordeling van de mate van obstructie voor IADSA en CA ongeveer gelijk zijn en beduidend lager dan in de literatuur wordt aangegeven.
- de chirurg op basis van de IADSA beelden vaker besluit tot het aanleggen van een bypass dan wanneer hij bij die beslissing alleen de beschikking heeft over CA beelden.
- het gebruik van IADSA bij het afbeelden van de onderbeensvaten in vergelijking met CA geen lagere stralingsdosis voor de patiënt tot gevolg heeft.
- onderbeensarteriografie met behulp van IADSA duurder is dan bij gebruik van CA.

