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A Delphi Consensus on Criteria for Contraindications, Assessment Indicators and Expected Outcomes Related to Tibialis Posterior Transfer Surgery[1]

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ABSTRACT

Ateam of experts in the field of reconstructive surgery for leprosy-affected people was identified. Using the Delphi method, an exercise was undertaken to ascertain whether a consensus on essential criteria and indicators for Tibialis Posterior Transfer (TPT) could be reached among the team. This paper describes the Delphi Exercise, giving results at each stage of consensus development. The final outcome was that essential criteria, including contraindications for surgery, pre- and post- operative assessments and expected outcomes, were agreed. The criteria are presented with recommendations.

RÉSUMÉ

Un groupe d'experts en chirurgie reconstructrice a été mis en place pour les patients souffrant de lèpre. En utilisant la méthode de Delphi, un exercice a été entrepris afin de vérifier si un consensus pouvait être atteint au sein du groupe au sujet des critères essentiels d'indication pour un Transfert du Tibialis Postérieur (TTP). Cet article décrit cet exercice selon la Méthode de Delphi et présente les résultats à chaque étape du développement du consensus. Le résultat final a été qu'un accord général a été obtenu sur des critères essentiels comme les contre-indications à la chirurgie, les évaluations pré et post-opératoires et les résultats attendus. Les critères sont présentés avec des recommandations.

RESUMEN

Para este estudio se contactó a un equipo de expertos en el campo de la cirugía reconstructiva para personas afectadas de lepra. Usando el método Delphi, se realizó un ejercicio para saber si el equipo podía llegar a un consenso sobre los criterios e indicadores esenciales para la Transferencia Tibial Posterior (TTP). En este artículo se describe el ejercicio de Delphi y se proporcionan los resultados obtenidos en cada etapa del desarrollo del consenso. El resultado final del ejercicio fue que hubo concordancia en los criterios esenciales, incluyendo las contraindicaciones de la cirugía, las valoraciones pre- y post-operatorias, y los resultados esperados. Se presentan los criterios y las recomendaciones del estudio.

It is generally agreed that treatment for leprosy is best integrated into the general health service provision. However, anecdotal reports from the field suggest that the decline in registered leprosy prevalence is impacting the scope of service provisions and the accessibility of referral services. The declining investment in leprosy may also impact professionals seeking to develop challenging careers. High profile health and development issues (e.g., AIDS, environmental challenges, etc.), which arouse wide public awareness and elicit strong financial support are likely to attract professional interest away from leprosy. The dilemma is compounded because high profile health and development issues, which arouse wide public awareness and elicit strong financial support, attract the interest of professionals seeking to develop challenging careers. Furthermore, much of the invaluable clinical experience and expertise that has hitherto been a resource to field programs is invested in relatively few exceptional people,

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many of whom are already embracing retirement. The transfer of knowledge and practice to ensure that a sound core of expertise is maintained is an issue. There is a considerable body of published evidence upon which a variety of clinical developments can be based, but certain procedures do not readily lend themselves to empirical investigation (e.g., criteria for assessments or the grading of outcomes). There is a compulsion to act expeditiously so that the wealth of wisdom and experience that does still exist may be tapped for present and future benefit.

Ameeting of an international group concerned with issues related to the measurement of disability was convened in Delhi in December 2002. Asub group, mandated with the responsibility of discussing issues related to the assessment and measurement of impairment, generated a number of research questions. One of the issues raised was that of standards for surgery. It was suggested that surgeons and therapists have there are widely differing views on criteria for the variety of surgical interventions commonly offered to people with the secondary effects of leprosy. It was agreed that, if possible, it would be beneficial to publish standard assessment criteria for two principle reasons: (i) to assist inexperienced surgeons who may need authoritative guidance; and (ii) to have standardized procedures so that comparative studies may be conducted.

Amethod to gather information for guidance which is less compromised than that of an individual's clinical experience in isolation is the Delphi method of consensus generation. Areview of the method is included in an article elsewhere in this JOURNAL (*Consensus Methods: A Bridge Between Clinical Reasoning and Clinical Research?* See page 28 for this editorial).

It was agreed by the sub group that an attempt should be made to apply the method to address the issue of assessment criteria for a common procedure for the correction of foot drop (tibialis posterior transfer a.k.a. TPT).

Some studies of the surgical procedure have been published. In 1981, Malaviya ([2]) compared Selvapandian's surgical method with Srinivasan's. (Malaviya reported follow-up of 78 cases from one to nine years and reported good results for either procedure in 70% of cases.) Malaviya emphasized the importance of post-operative physiotherapy as an important factor influencing outcome. When current protocols were reviewed for this study it was found that physiotherapy assessment criteria, and outcome indicators generally differed between institutions.

Bari, *et al*. ([1]) conducted circumtibial transfer of tibialis posterior and chose "heel toe gait restoration" and "active dorsiflexion" as indicators of success. Soares ([3, 4]) compared circumtibial with interosseous methods of tendon transfer. The outcome he was primarily interested in was recurrent inversion deformity. From the review of current assessment protocols, it was found that the restoration of heel toe gait and dorisiflexion were common but inversion deformity was not. (In the final draft, the occurrence of inversion deformity is considered to represent a "failed" procedure).

Acriterion that was noticeable by its absence in current assessment protocols was client satisfaction. Weber, *et al*. ([5]) studied 25 cases of TPT using levels of patient satisfaction as the outcome of interest. Finding that 18 were satisfied but 7 were not, Weber considered the procedure to be appropriate in a developing country (his study was undertaken in Pakistan).

The findings in all the studies cited above would have been strengthened if assessment methods had been standardized and a wider set of outcomes had been considered.

METHOD

Alist of names of internationally recognized surgeons and therapists was gathered. Thirteen people were requested to consider participation in the process. Three declined but the remaining nine committed themselves to participation in, and the outcome of the Delphi Exercise. The participants, hereafter referred to as the "Delphi Team," remained anonymous throughout the investigation to comply with the demands of the Delphi Exercise.

The Delphi Team comprised: Dr. J. W. Brandsma RPT, PhD, Consultant Physiotherapist, International Nepal Fellowship, Nepal; Dr. M. Ebenezer MBBS, D.Ortho., M.S(Ortho), Senior Specialist and Deputy Director, Schiefellin Leprosy Research and Training Center, Karigiri, India; Dr. R. Kazan, MD, Formerly Head of Surgery ALERT, Addis

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The Sequence of developments in the Delphi Exercise:

Stage 1. An initial letter explaining the Delphi process and inviting participation was sent, by email, to potential Delphi members. The message had a request that, should they agree to participate, they should submit any contemporaneous TPT assessment forms known to them.

Stage 2. Collation of information from assessment forms.

Stage 3. Dispatch of collated criteria for rating by Team Members.

Stage 4. Scoring of results from rating exercise.

Stage 5. Dispatch of agreed criteria for further refinement by Team Members: i.e., contraindications, assessment indicators and expected outcomes.

Stage 6. Collation of results from refinement exercise

Stage 7. Dispatch of Draft "Gold Standard" Criteria for final consideration by Delphi Team.

Stage 8. Final adjustments to Gold Standard in accordance with feedback from Delphi Team.

Stage 9. Presentation of final product (Gold Standard) to the Delphi Team.

Stage 10. Dissemination of the Delphi Exercise outcome.

Stages 1 and 2: *Collation of Information.* Eight people submitted assessment forms from which information was collated by the coordinator. Alist was compiled which included all the criteria contained in the various forms. On examining the assessment forms, it was apparent that the process of assessment progressed through stages with key components taking prominence at each stage. Atotal of 69 discrete criteria for screening and pre-operative assessment were identified in the assessment forms that had been submitted. These criteria applied to five essential stages of assessment, which were identified as: (i) Initial Screening; (ii) Pre-Physiotherapy—Psycho-Social; (iii) Pre-Physiotherapy—Physical; (iv) Pre-Physiotherapy—Physical—Muscle Grading (MRC); and (v) Pre-Operative Screening.

From the assessment forms that were submitted only 16 of 69 criteria were common to 5 or more forms.

TPT assessment forms included post operative assessments. The number of discrete criteria identified in post-operative assessments was 44, but only 3 criteria were found to be common to 5 or more of the forms submitted.

Stage 3. All discrete criteria were tabulated. The task, as explained to the Delphi Team, is given below (Note. Full tables available on-line from the ILAwebsite, www.leprosy-ila.org. They may also be obtained from the author.)

(i) The tables contained lists of all the criteria collated from the assessment forms that were sent to the coordinator.

(ii) Eight people had submitted forms that were in use, at divers' institutions, at the time of the exercise. Where 5 or more people submitted forms that contained the same criteria, such criteria were considered "essential." These criteria were listed in the table but did not require any further consideration.

(iii) Acolumn denoted "F" was included. The number related to the number of forms from different institutions where a particular criterion was already being used.

(iv) Each team member was required to rank every criterion except those that were already accepted as "essential." The rank options were: Should be omitted, Not Useful, Neutral, Useful, and Essential.

Team members were informed that it would be assumed that personal details of patients (including hospital number, etc.) would be included in all assessments, along with the name of the person undertaking the assessment. It was also assumed that the general health of the patient will be assessed before consideration of surgery. Criteria relating to General Health, therefore, were not included either. Team members were reminded, however, that an aim of the exercise was to produce an assessment form that could be used with confidence by surgeons and therapists who may have limited or no experience with leprosy.

Stage 4. Nine people responded to the request to complete the task of ranking the criteria.

Each rank was given a score. Descending negative scores were given where members had ranked a criterion as either "Not useful" or "Should be omitted." If a criterion was ranked as "Neutral" it was scored as 0. Ascending positive scores were given where members had ranked a criterion as either "Useful" or "Essential." With nine members contributing, the final score for each criterion represented the mean of the nine responses.

Criteria were judged as follows:

Score <1. The indication was that the criterion is *Not Acceptable* and should be rejected.

Score >1<2. The indication was that the criterion is *Acceptable* and should therefore be included for further consideration.

Score >2<3. The indication was that the criterion is *Useful* and should therefore be included.

Score >3. The indication was that the criterion is *Essential.*

Stage 5. All criteria meeting acceptance were tabulated and resubmitted to the Delphi Team for their information (please see Appendix 2). Two criteria were withdrawn because they caused confusion (gauged by comments from team members).

This stage of the exercise also required that the Delphi Team should again consider the criteria and state how the criteria should be used as indicators and contra-indicators for surgery. Post operative assessment criteria were also tabulated with key assessment times (according to the group vote). The Delphi Team was asked to consider the criteria for assessment and, to give a concise description of expected outcomes.

Stage 6. *Contraindications for TPT surgery.* Eight people submitted suggestions for contraindications. Where 4 or more people identified the same or similar contraindication, the suggestion was recorded as an "absolute contraindication." Where fewer than 4 people submitted a suggestion, the contraindication was recorded as a "relative contraindication."

Expected Post Operative Outcomes. While similar in meaning, the outcomes that were submitted were different in the way they were expressed. This was due mainly to the method, which at this stage was more open to personalized expression. To tabulate the expected outcomes, the most representative expression of an item was selected by the coordinator. The manner in which items were represented was also edited for clarity and conformity by the coordinator.

Stage 7. On receipt of the responses from stage 6, the assessment criteria, with contraindications, were again tabulated as were the expected outcomes. These tables were resubmitted to the Delphi Team as "the draft Gold Standard." Assurance was given that should 4 or more people request changes to any one item in the tables, such requests would be implemented (this was because the wording had been edited by the coordinator and was therefore subject to his interpretation). It was reiterated, however, that the screening, assessment and outcome criteria per se were no longer negotiable (see Appendix 3).

At this stage, team members were made known to each other and the process was opened for discussion should the team wish to inter-relate, mindful that the objective of the exercise was to present a consensus on criteria that could be recommended as "Gold Standards" for TPT protocol. The aim was not to produce an actual protocol, but that the criteria should represent the key elements for prospective protocols (actual protocols will be institution-specific).

Members were requested to consider the following options and then to indicate their choice to the coordinator: (i) Endorse the elements as they stood. (This was to be the preferred choice if members were satisfied with the contraindications, assessment criteria, and expected outcomes as given in the

draft "Gold Standard." If at least 70% of the members agreed to endorse the criteria then the element would be presented as a "Gold Standard."); (ii) Endorse the elements, but offer personal comments to augment them; (iii) Request delay of endorsement pending further discussion; (iv) Reject the elements.

Stage 8. Nine members responded to the request for refinement of the draft "Gold Standard." Three members endorsed the elements as they stood. Six others had some criticism of, or sought clarification of different criteria, but no criterion had more than 2 requests for the removal or alteration of the criterion. None of the members expressed dissatisfaction with the outcome in its entirety.

In response to requests, the coordinator altered the wording of three elements that had consistently caused confusion.

Stage 9. The final draft of Gold Standard Criteria for TPT was circulated to all members with expressions of gratitude for their collaboration.

Stage 10. Papers drawn from the process and outcome of the exercise were written up for publication.

RESULTS

On the basis of consensus as described in Delphi methodology, a list of criteria was agreed on by a panel of recognized experts. The list includes:

- Criteria for the initial screening of potential candidates for Tibialis Posterior Transfer (foot drop correction). There are 10 essential criteria that should be considered when screening patients for suitability for surgery. Relative and absolute contraindications (or both) are given (Table 1).
- Pre-operative assessments. There are 20 criteria that should be considered essential aspects of examination before physiotherapy to prepare a person for surgery, and 5 essential criteria that should be satisfied during a surgeons pre-operative examination. For each of these examination criteria, either a relative or absolute contraindication (or both) are given (Table 2).
- Post-operative assessments. There are 17 essential criteria that should be examined post-operatively. Expected outcomes at periods after surgery are given (Table 3). Key post operative dates are fixed at: (i) one day after plaster of Paris removal; (ii) four weeks after post operative physiotherapy; (iii) between 3 to 6 months after post operative physiotherapy.

DISCUSSION

Sound empirical evidence is the most reliable basis on which clinical practice should be developed. There are situations, however, where the authority of individuals is validated by peer recognition of their experience and expertise. It is not sound to recommend practice based on the reputation of a single individual. Where a homogenous group of recognized experts can develop and endorse recommendations, however, the outcomes have internal validity and can be recommended. The validation of standardized assessment criteria will, furthermore, facilitate comparative studies which may yield empirical data that will further enhance the development of clinical practice.

Delphi is a method of consensus development among homogenous groups. While the design does control the negative effects of open group interaction it does also lose some of the positive effects of open interaction: e.g., idea generation. In this study, some members registered frustration with the isolation demanded by anonymity and seclusion and suggested that they would have preferred direct discussion and personal interaction. However, domination and control were avoided by the process thus allowing greater freedom of expression by some who may otherwise have perceived threat.

ADelphi Exercise is often protracted. The investigation presented here took 18 months to complete. The principal reason for this problem was the demands on the time of individuals in the Delphi Team. Without the immediacy and urgency dictated by the constraints of a physical meeting, members may be distracted from the task to attend to more pressing matters. However, an advantage of the method is that it can draw on the resources of individuals from diverse locations without the costs and inconvenience of physically assembling an international group.

TABLE 1. *Screening for TPT Candidates*

Criterion	Absolute Contraindication	Relative Contraindication
Pre-Physiotherapy—Determine Leprosy Status		
Treatment status	Patient has not completed 3 months of PB leprosy treatment or 6 months MB leprosy treatment	Patient is currently taking MDT treatment
Duration of paralysis		Less than 6 months (If uncertain of duration, query neurological testing and treatment given before proceeding)
Pre-Physiotherapy—Determine Neurological Status		
Monofilament Sensibility Test		
Is there a history of reaction in the previous 6 months	Patient has presented with reaction, or acute neuritis within 6 months prior to consideration for surgery.	
Has the patient been on steroid treatment within the previous 6 months	Patient has received steroid therapy within 3 months prior to consideration for surgery	
Pre-Physiotherapy—Psycho Social Screening		
What is the patient's occupation		
Does the patient understand: • Objectives of surgery • That surgery will not change loss of nerve modalities • That active collaboration will be required for successful outcome		• Patient appears to have unrealistic expectations • If there is no understanding of requirement for active participation surgery should be delayed until a clear understanding and commitment can be assured
Does the patient understand and accept:		
• Time required (including pre and post operative physiotherapy)	Patient cannot commit to at least 1 month inactivity (work, family obligations or distance may prohibit)	Patient shows disinterest to do adequate pre surgical training and preparation
• Time of reduced activity required before resuming normal activity		
Can the patient demonstrate adequate self care		Does not practice Self-care
Has there been an assessment of the activities of daily living and the patients participation in social activities		

TABLE 2. *Examination of TPT Candidates*

Criterion	Absolute Contraindication	Relative Contraindication
Pre Physiotherapy—Physical Examination		
Any signs (or history) of neurological bone disorganization	Active neurological bone disorganization (NBD)	History of NBD
Skin Condition	Ulceration, fungal infection or dermatitis on the foot to be operated on	Ulceration on any other body part
Any other eye hand or foot impairments		Inability to use crutches
Is there any contracture of plantarflexor muscles	Joint Limitation / block restricting dorsiflexion (May be addressed prior to surgery)	
What is the position of the foot at rest (inverted or everted)	If the foot is fixed in either inversion or eversion	
Define quality and range of motion at foot joints other than the ankle joint		
Define gait pattern		Apparent CNS problems causing gait changes (spasticity)
Describe arch architecture		
Ascertain whether patient can use crutches		
Describe the type of footwear that has been used and the duration of usage		
MRC Grading:		
Tib. Anterior		
Ext. Hal. Longus		
Ext. Dig. Longus		
Flex. Hal. Longus		
Flex. Dig. Longus		
Per. Longus		
Per. Brevis		
Tib. Posterior	Less than MRC grade 4	
Tendo Ach. / Gastochnemius		
Is there evidence of claw toes		
Pre Operative Examination		
Skin condition	Ulceration, fungal infection or dermatitis on the foot to be operated on	Ulceration on any other body part
Passive dorsiflexion / Knee in flexion / Knee in extension		
Active dorsiflexion / Knee in flexion / Knee in extension		
Active plantarflexion		
Passive range of motion (ankle)	Exclude if <10 deg dorsiflexion (unless caused by correctable contracture)	

TABLE 3. *Post Tibialis Posterior Transfer Assessment*

Criterion	Expected Outcomes and Considerations		
	1 Day after POP removal	After 4 Weeks Physiotherapy	Between 3 to 6months
Position of foot at rest (eversion / inversion)	NANeutral to slight eversion		Neutral to slight eversion
Active range of motion/Knee in flexion	NA	20 degrees dorsiflexion with recovering plantarflexion	Between 10 and 20 degrees dorsiflexion with between 10 and 20 degrees plantarflexion
Passive dorsiflexion / Knee in extension	20–25 degrees from ankle neutral	15 to 20 degrees from ankle joint neutral	20 to 30 degrees from ankle joint neutral
Active dorsiflexion / Knee in extension	Partial (0 –10 degrees)	10 to 20 degrees (minimum 10) from ankle joint neutral (90 degrees)	10 to 20 degrees (minimum 10) from ankle joint neutral (90 degrees)
Gait pattern	NAA	ble to bear full weight, heel to toe	heel to toe gait
Active Plantarflexion	NA	10–20 degrees from ankle joint neutral	10–20 degrees from ankle joint neutral
Able to walk normally (short distance)	No walking	Normal walking	Normal walking
Able to squat	No squatting	Not to be encouraged	Should be able to squat
Arch architecture	Normal	Normal: i.e., should resemble pre op architecture	Normal: i.e., should resemble pre op architecture when non weightbearing
Inversion with dorsiflexion	If present the procedure is a failure		
Eversion with dorsiflexion	No	No	No
Signs of, neurological bone disorganization	NACheck foot after beginning weight	bearing and intervene if needed	This should be expected occasionally, but it is not necessarily due to surgery
Signs of ulceration on lateral border		Check and take needed intervention. Sign will indicate poor therapy	Check and take needed intervention This outcome should be expected occasionally
Inversion deformity			This outcome should be expected occasionally
Suitability of Footwear/orthosis *This item should be checked. It is not an outcome*	NA	Appropriate tie up (or velcro) shoe with orthosis	Appropriate tie up (or velcro) shoe with orthosis

Control of coordinator bias can be an issue. It is imperative that the coordinator of the Delphi Team maintains complete impartiality and strives to ensure that all submissions are correctly interpreted and that all requests for clarification are conveyed. It is preferable that when a Delphi Exercise is commissioned, a coordinator is appointed who will not have a vested interest in the outcome of the process. Presenting ideas unambiguously and with sufficient clarity for all members to grasp is an essential and demanding task. For this reason simplicity and brevity are recommended.

Consensus does not imply unanimity. It is the product of negotiation and compromise and represents a general agreement. Not all the members of the Delphi Team endorsed all the criteria recorded (although only a very few criteria evoked criticism). The final outcome is a valid reflection of the corporate opinion of the experts who participated in the Delphi Exercise. Individual therapists and surgeons will add features that they may consider will give more detailed information on a case by case basis.

CONCLUSION

Aconsensus was reached on the essential criteria to be considered when surgeons and therapists are planning and executing Tibialis Posterior Transfer to address the problem of foot drop. That the exercise was necessary is supported by the observation that the pre- and post-operative protocols that were submitted at the start of the exercise differed greatly in the assessment criteria used.

The outcomes are presented with two recommendations: (i) best practice can be developed on the basis of the criteria suggested; and (ii) comparative studies of the TPT procedures will benefit from standardized protocol based on the recommendations of the Delphi Team.

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