Journal of Geriatric Physical Therapy PROGNOSTIC IMPLICATIONS OF PRE-DISCHARGE ASSESSMENT OF GAIT SPEED AFTER HIP FRACTURE SURGERY

--Manuscript Draft--

Manuscript Number:	JGPT-D-16-00109R6		
Full Title:	PROGNOSTIC IMPLICATIONS OF PRE-DISCHARGE ASSESSMENT OF GAIT SPEED AFTER HIP FRACTURE SURGERY		
Article Type:	Research Reports/Quantitative		
Keywords:	hip fracture; functional recovery; 4-m walking test; prognosis.		
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Manuscript Region of Origin:	ITALY		
Abstract:	Background and Purposes: Hip fracture represents one of the most severe injuries in the older adults. In long-term survivors, disability is common and evaluation of walking ability may be considered as an important predictor of functional recovery. We therefore investigated if 4-m gait speed, assessed in older persons early after surgical repair of hip fracture, could predict functional recovery and subsequent development of major clinical outcomes. Methods: This is a prospective cohort study design. We included adults aged 65+ years, admitted to a community acute care hospital with hip fracture, undergoing surgical repair. As soon as the participant was able to stand and walk, using walking aids as needed but with no person's help, the 4-m walking speed was tested as the main predictive variable. The outcome variables included: the change in the Barthel Index (BI) from pre-hospital through 1-year postoperatively as a continuous variable and two dichotomous outcomes, i.e.: 1) a decrease in BI greater than 5 points in 1 year and 2) a composite end-point, combining 5+ points BI decline, death, falls, institutionalization, and need for 24-h home assistance in 1 year. Results: 62 participants (mean age 85 years) were enrolled and evaluated, on average 6 days (SEM=0.2) after hip fracture surgery. Compared to pre-fracture (96.3 SEM=0.9;), BI decreased 1 month after surgery (76.5 SEM=2.1) and recovered only		

partially at 2 (84.1 SEM=2.2) and 12 months (87.2 SEM=2.8). A pre-discharge value of the walking speed below the median (20.5 cm/sec) predicted a substantial BI reduction throughout the 12 months. Furthermore, the adjusted risk of a decline in the functional status was reduced by 5% (OR 0.95, 95% CI 0.91-0.997, p=0.038), and that of the combined outcome by 7% (OR 0.93, 95% CI 0.88-0.99, p=0.013), per each cm/sec of pre-discharge walking speed.

Discussion and Conclusion: The 4-m walking speed, measured early after surgical repair of hip fracture, has profound long-term prognostic implications. This assessment approach might prove helpful in clinical decision-making on the post-operative management of older hip fracture persons.

Response to Reviewers:

Dr. Richard Bohannon

Editor

Journal of Geriatric Physical Therapy

Comments:

1.Indicate the highest degree of the PT authors.

This was corrected to the best of our understanding. Thank you.

2. Shorten the Background and Purpose of the ABSTRACT by at least a third. The second sentence states a tautology.

The paragraph was changed accordingly to suggestion of the Editor. Thank you.

3. The Barthel Index is not a continuous measure.

We totally agree that the Barthel Index is an interval discrete, not continuous, measure. However, we never declared Barthel Index as a continuous measure: we have examined our manuscript thoroughly, also looking for the words "continuous" and "Barthel", yet we could not find any place were the two are together. On pages 4 and 6 we did speak of gait speed as a continuous variable, in some proximity with the BI abbreviation, but the adjective clearly refers to gait speed, not to the BI.

4. You can limit dispersion measures (eg, SEM) to the tenths place (eg, 0.9 rather than 0.87).

Done. Thank you.

5. Eliminate passive voice (eg, "It has been reported.").

Done. Thank you.

6. The x- axis for the figure should be designated as: Time, mo

Done. Thank you.

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Prof. Mauro Di Bari

To Richard W. Bohannon, PT, EdD, NCS, FAPTA, FAHA, CEESS, USA Editor, *Journal of Geriatric Physical Therapy*

Sir,

Enclosed please find a fourth version of our manuscript entitled "Prognostic implications of pre-discharge assessment of physical performance in older patient after surgery for hip fracture", which we submit to you for consideration as a Quantitative Research Reports in JGPT. The paper has been further revised according to your suggestions, some of which are not entirely new and had been indeed addressed in our previous responses. We sincerely hope that the paper will be now considered appropriate for the JGPT.

Below please find our response to the issues raised; changes have been marked as a bold text in the manuscript.

Editor Comments:

• On the Title Page provide the highest degree for the PTs.

This request is not new. As per our e-mail sent to the Editor on October 2, 2016, attached to the present letter, we asked for clarification on what is missing; unfortunately, we did not receive answer and, therefore, we could not, and cannot, provide the information requested. Further clarification will be more than welcome. Thanks.

• In the ABSTRACT, line 29, I think the authors mean 4 meter rather than 4 minute.

Done. Thank you.

On page 3 "intensive care unit" does not require capitalization.

Done. Thank you.

• On page 7 we prefer the term attrition to drop-outs.

Done. Thank you.

• There may be an author problem with reference 26

Done. Thank you.

• In Table 1 capitalize Mean and Range

Done. Thank you.

Reviewer 2.

Abstract

1) Sentence 1 - please remove "the" older adults and place a comma after adults

Done. Thank you.

2) Sentence 4- over a short distance (not on)

Done. Thank you.

3) Sentence 4- to estimate a subsequent clinical course (add a)

The sentence was changed accordingly to suggestion of Reviewer 3. Thank you.

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Prof. Mauro Di Bari

Methods of Abstract

4) We included adults (add an s to adults)

Done. Thank you.

General comments:

- 5) What was the weight bearing status of these patients with hip fracture? Please make that clear.
- 6) Did they have any hip precautions that would restrict them from the outcome measures used?

All the participants that could perform the 4-m walk test had a partial weight bearing status, as it can be expected in a very early phase after hip fracture surgery. When the test could not be performed, this was due to a compromised general status and never to inability to sustain weight or to hip precautions restricting them from collecting outcome measures.

7) What is pre-fracture? (Did you screen all of these participants as community dwellers with the BI prior to their fall/injury/hospitalization? The pre-fracture data collection still remains unclear to the reader. Elaborate on this please.)

Information of pre-admission (or pre-fracture) status, including the BI, was collected on admission, as part of medical and functional history, and it was referred to 15 days prior to fracture. In the current version of the manuscript, this had been described on page 3, Methods, Data Collection second sentence; for the sake of clarity and better understanding, we have further specified this point in a previous section of the Methods sentence starting with "Most of base line...". No screening of the participants as community dwellers had been performed.

8) Throughout the paper articles a, an and the are missing frequently.

This was corrected to the best of our understanding. Thank you.

9) Line 44 in Methods, trial not trail

Done. Thank you.

10) P.5 line 5 enrollment is misspelled

We did change this according to the reviewer's request, although most dictionaries admit both forms. Thank you.

Reviewer 3.

11) Overall, I believe this manuscript adds to the literature base for the Physical Therapy profession in an area in great need of research - that is prognostic biomarkers that may be used to foretell long term outcomes and potential areas for greater intervention to mitigate the lower functioning cohort below the dichotomous cut points. Some revisions need to be made to clarify the protocol used for measuring gait speed as there are numerous gait speed protocols and the one described here based off of SPPB is not described as the SPPB. The test described here where the timer is started on the word, "Go" does not accurately capture speed alone, but also captures cognitive processing time and acceleration time. Whether this change in protocol is statistically significant or not we cannot ascertain. Additionally, reliability and validity data supporting use of this test measure is absent. However, with that said, the results comparing pre dc speed and Barthel index measures across the 4 time points, anecdotally make sense. The methodology chosen is reasonable.

The point the reviewer raises is well taken and we acknowledge that our current description is misleading as far as procedures for the 4-m walk. As a matter of fact, we did apply the standard SPPB protocol, including instruction to the participants to walk at their usual speed as if they were going to the shop. We apologize because our previous description was imprecise, as timing started as the participant began to walk after the "Go!" order. This imprecision derived from an attempt to differentiate our protocol from others, which prescribe to have the participants start walking before the 4-m path and to start timing when the first marker is crossed; yet, in doing this, we might have erroneously induced the thought that the we included in our timing the possible delay between the "Go!" order and the

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actual beginning of the walk. Thanks to the reviewer's remark, we noticed this imprecision, which has been now amended.

12) I would like to see an expansion on reliability of this gait measure, add more to the methodology regarding who collected the data, blinding?

Because, as we explained before, the standard SPPB protocol was indeed applied, answer to this request is no longer entirely needed. As far as blinding, personnel who collected follow-up data was blinded to baseline assessment; this was added second last sentence in Methods, section Participants and Study Protocol.

Who made the follow up phone calls?

All the calls were made by the same person, i.e. the first author of the study.

Specifics

PAGE 1:

13) Line 9. How common? Please add a reference and give percentages.

We do not feel that adding this information in the Abstract is really needed and appropriate, whereas we have added prevalence of disability figures on page 2 (third sentence in the Introduction), in the new version. References (#3 and #4) were already cited.

14) Line 14. Recommend changing the word biased to subjective. Remove poorly reliable unless you have a reference to support this.

We changed the adjective "biased" into "subjective" as required. As per our response to the previous point, we did not add a reference to the abstract. Please note on page 2, Reference #9.

15) Line18. Did you address a clinical course or more specifically outcomes at endpoints? You did not track the interventions through the course, did you?

We changed the term "clinical course" into "functional evolution and clinical outcomes" as required.

16) Line 33. Please clarify how you addressed functional status at 1 year differently than using Barthel Index. I would rather see the word decline changed to "change" over one year.

We have now changed our phrasing, specifying that the BI score was taken as a continuous variable or, alternatively, as a dichotomous variable (>5-point change). We changed "decline" with "change" as required.

17) Line 51. Not everyone was measured for gait speed at day 6 according to P3 Line 33. Please clarify this statement.

We changed "6 days" into "early after surgery".

PAGE 2:

18) Line 27. Please explain how you have floor or ceiling effects with qualitative data.

Our apology for being unclear. The term "observational" gait assessment is preferable to "qualitative" in the given context. This change was made.

- 19) Line 29. Agreed.
- 20) Line 38. This is not addressed in the conclusion paragraph. Did you fine a correlate your gait speed measure/Barthel Index to mortality or institutionalization?

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Prof. Mauro Di Bari

What we wrote in the Introduction, is exactly reported in the final Conclusions paragraph, page 8, with the only difference of the words "such as institutionalization or death", which were omitted for the sake of conciseness.

The second part of this reviewer's comment is unclear, possibly also because of some typos. From what it can be argued, the reviewer uses the term "correlate" when, in fact, "association" was meant, being mortality and institutionalization dichotomous variables, not amenable to correlation analysis. Moreover, what he/she asks around gait and BI is questionable, because these two variables have a completely different meaning in our study, being the first an explanatory variable, the second an outcome variable.

21) Line 51. Do you select the BI of <50 or is there research out regarding this cut point? Do you have reliability/validity data for this measure?

As per our previous rebuttal letter, "We have specified that the exclusion of patients with a pre-fracture BI<50 was not an authors' choice, but rather an admission criterion routinely applied to the Orthogeriatrics Unit where the study was done." This is clearly stated also in Methods section Participants and Study Protocol, of the current version of the manuscript. With our most sincere apology, we cannot do more than reiterate that this criterion derives from our hospital admission policy, with no reliability/validity data for it.

PAGE 3:

22) Line 2. How was this history information obtained?

This information was obtained from routine hospital records. This was further clarified. A comment was added in the Discussion on this issue.

23) Line 5. How did you determine cognitive status? It is stated in the data collection but, needs to be mentioned here regarding MMSE and the validity/reliability and cut points selected.

In the new version, use of MMSE is mentioned earlier than in the current version. Because this information was obtained from routine hospital records, we cannot provide reliability/validity data on it: this was mentioned as a study limitation in the Discussion (page 8, sentence starting with "Moreover most variables...").

24) Line 13. Who gathered the data? One researcher? Blinding? Reliability of data collector? How did you ensure fidelity for test administration and data collection?

See response to point 22.

25) Line 38. The gait speed protocol described here does not match the SPPB protocol which asks a person to imagine walking down the street to a store and then again asks walking at usual pace. Additionally, the timer starts on movement and not on the word go. Please clarify this protocol. Please address the fact that your protocol includes cognitive processing time and acceleration time in the measure. Other gait speed protocols have acceleration and deceleration zones before and after the gait speed track respectively, so that the measure is steady state speed. This needs to be addressed along with validity/reliability.

Please see our response to Reviewer 3, point 11.

PAGE 5:

26) Line 31. Do you have any data on pain levels, weight-bearing status, etc.? Also, was there a difference between replacement and fixation on Barthel Index scores?

Unfortunately, detailed data on pain level were not systematically collected. As far as weight bearing status, please refer to our answer on point 6. As far as potential effects of type of surgery (replacement vs. fixation) on BI (but also on other outcomes), this was specified in the current version of the study, page 4, Methods, towards the end of the paragraph Analytic Procedures.

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Prof. Mauro Di Bari

27) Line 44. Any data on the interventions of physiotherapy? Any differences between gait speed/barthel based on practice setting or other differences?

As far as potential effects of physiotherapy on BI (but also on other outcomes), this was specified in the current version of the study, page 4, Methods, towards the end of the paragraph Analytic Procedures.

PAGE 6:

28) Line 1. Does completely unable to walk meaning bed bound or chair bound?

This information is not available in our database. We wonder how this would impact on our findings: we did not examine the prognostic impact of pre-discharge functional status as an ordinal variable (e.g., bed-bound vs. chair-bound vs. minimally ambulatory vs. fully ambulatory ...), but the effect of an objective, quantitative assessment of walking ability. A gait speed of zero compares to walking speeds greater than zero regardless of the ability to sit on a chair or not.

29) Line 35. What do you mean by combined outcome?

The word "combined" was used on this line as a synonymous of "composite". For the sake of clarity, in the revised version we now stick with the term "composite" without using synonymies.

PAGE 7:

30) Line 20. "Substantially" is a strong word for a study with an N of 62. Was a power analysis performed?

We deleted the adverb. Nevertheless, we would respectfully note that the substantial novelty of the finding has nothing to do with power analysis. We are well conscious of the limit represented by our small sample size, and we did declare this as a major limitation in page 8, in the last part of our Discussion.

31) Line 44. Do you mean recovery or "outcome measures"? Isn't recovery the process. You measured outcome measures at specified time points but, did not look at the entire year.

"Functional recovery" has been changed with "functional evolution", an expression that is present in other parts of the current version and was not criticized by the reviewer. However, we would respectfully observe that measuring outcomes at specified time points is a way to assess the recovery process across an entire year.

PAGE 8:

- 32) Line 36. Agree with the statement regarding N size.
- 33) Line 56. This is a very brief summary. Recap of gait speed differences and Barthel differences need to be wrapped up. What does the study add to the literature base?

Conclusions were expanded. Thank you for giving us the chance to elaborate, contrary to what is usually requested, i.e.: shorten, being concise, cut!

Thank you again, sincerely, for your time and consideration.

Florence, May 7, 2017

HL.

Mauro Di Bari, MD, PhD (corresponding author) Associate Professor of Medicine – Geriatrics Research Unit of Medicine of Aging Department of Experimental and Clinical Medicine University of Florence

DIPARTIMENTO DI MEDICINA SPERIMENTALE E CLINICA UNITÀ DI RICERCA DI MEDICINA DELL'INVECCHIAMENTO

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Prof. Mauro Di Bari

ANNEX - E-MAIL PREVIOUSLY SENT TO THE EDITOR

Da: Mauro Dibari <mauro.dibari@unifi.it>

Oggetto: Re: Please provide changes to your JGPT submission

Data: 2 ottobre 2016 18:45:31 CEST A: JGPT <rbohannonpt@gmail.com>

Cc: Sara Gherardini <sara.gherardini@uslcentro.toscana.it>

Dear Dr. Bohannon,

thank you very much for your prompt answer and constructive suggestions, which we will be definitively follow to improve our work. I'm confident that in a couple of weeks we will provide you a revised version.

I'd like to ask you a clarification on what you expect as "highest degree", as per point 2. After many many years of scientific activity and several publications in international journals, this is the first time I've been asked for such a specification.

Thank you again. Sincerely yours.	
Prof. Mauro Di Bari	
Mauro Di Bari, MD, PhD	

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MacAir

Il giorno 27 set 2016, alle ore 22:31, JGPT < em@editorialmanager.com > ha scritto: 09/27/2016

Dear Professor Di Bari,

Your submission entitled "PROGNOSTIC IMPLICATIONS OF PRE-DISCHARGE ASSESSMENT OF GAIT SPEED AFTER HIP FRACTURE SURGERY" has been received by Journal of Geriatric Physical Therapy. The work is within the scope of the Journal, but corrections are required before I am willing to assign an Editor.

Please address the following concerns and resubmit your paper:

1)The submission letter refers to JAGS. I suspect you neglected to edit the Journal when you submitted your paper.

DIPARTIMENTO DI MEDICINA SPERIMENTALE E CLINICA UNITÀ DI RICERCA DI MEDICINA DELL'INVECCHIAMENTO

Prof. Mauro Di Bari

CA DI MEDICINA DELL'INVECCHI



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2)On the Title Page the professional designation and highest degree needs to be indicated for each author. You provide the former but not the latter.

- 3)We prefer that the term subjects not be used. Older adults, individuals, etc are preferred as dictated by the situation.
- 4)It is not sufficient to say ethics approval is not required. It's not up to the authors to exempt a study. It is up to the ethics committee or established law/regulations.
- 5)Remove spaces between sections of the manuscript.
- 6)Use numerals (eg, 2) rather than words (eg, two) for numbers.
- 7) Contiguous reference numbers can be presented using a dash (eg, 12-16).
- 8)You should consider using ROC analysis to identify the bet gait speed cutscore for predicting your dichotomous outcome.
- 9)Fix reference 9.
- 10) Journal style calls for units to be presented after a comma rather than in parentheses (eg, Walking speed, cm/s). Style also calls for Mean and SD/SEM to be presented as Mean (SD) rather than Mean +- SD.
- 11)Braden et al have measured gait speed in acute care, albeit not for a sample limited to patients with hip fracture (Braden HJ et al. Gait speed is limited but improves over the course of acute care physical therapy. J Geriatr Phys Ther 2012; 35(3): 140-144.)

Here are any Digital Artwork Quality results obtained by Editorial Manager: Figure (Word 97-2003 Compatible Document) Figure 1-Gherardini.doc:Untested

Please be sure to make any necessary corrections to your figures prior to resubmitting your manuscript.

Please log onto Editorial Manager as an author. The URL is http://jgpt.edmgr.com/.

Kind Regards,

Richard Bohannon, PT DPT EdD NCS FAPTA FAHA FASNR FAACPDM CEEAA Editor

Journal of Geriatric Physical Therapy

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	✓ (a) Indicate the study's design with a commonly used term in the title or the
		abstract
		✓ (b) Provide in the abstract an informative and balanced summary of what was
		done and what was found
Introduction		
Background/rationale	2	✓ Explain the scientific background and rationale for the investigation being reported
Objectives	3	✓ State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	✓ Present key elements of study design early in the paper
Setting	5	✓ Describe the setting, locations, and relevant dates, including periods of
		recruitment, exposure, follow-up, and data collection
Participants	6	✓ (a) Give the eligibility criteria, and the sources and methods of selection of
		participants. Describe methods of follow-up
		(b) For matched studies, give matching criteria and number of exposed and
		unexposed
Variables	7	✓ Clearly define all outcomes, exposures, predictors, potential confounders, and
		effect modifiers. Give diagnostic criteria, if applicable
Data sources/	8*	✓ For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if
		there is more than one group
Bias	9	✓ Describe any efforts to address potential sources of bias
Study size	10	✓ Explain how the study size was arrived at
Quantitative variables	11	✓ Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
Statistical methods	12	 ✓ (a) Describe all statistical methods, including those used to control for confounding
		✓ (b) Describe any methods used to examine subgroups and interactions
		✓ (c) Explain how missing data were addressed
		✓ (d) If applicable, explain how loss to follow-up was addressed
		(e) Describe any sensitivity analyses
Results		
Participants	13*	✓ (a) Report numbers of individuals at each stage of study—eg numbers potentially
-		eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed
		✓ (b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	✓ (a) Give characteristics of study participants (eg demographic, clinical, social)
•		and information on exposures and potential confounders
		✓ (b) Indicate number of participants with missing data for each variable of interest
		✓ (c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	✓ Report numbers of outcome events or summary measures over time
Main results	16	✓ (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders
		were adjusted for and why they were included

		✓ (b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period
Other analyses	17	✓ Report other analyses done—eg analyses of subgroups and interactions, and
		sensitivity analyses
Discussion		
Key results	18	✓ Summarise key results with reference to study objectives
Limitations	19	✓ Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	✓ Give a cautious overall interpretation of results considering objectives,
		limitations, multiplicity of analyses, results from similar studies, and other
		relevant evidence
Generalisability	21	✓ Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	✓ Give the source of funding and the role of the funders for the present study and,
		if applicable, for the original study on which the present article is based

^{*}Give information separately for exposed and unexposed groups.

PROGNOSTIC IMPLICATIONS OF PRE-DISCHARGE ASSESSMENT OF GAIT SPEED AFTER HIP FRACTURE SURGERY

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Conflict of Interest and Source of Founding: The authors declare no conflicts of interest and had no sources of funding for this study.

PROGNOSTIC IMPLICATIONS OF PRE-DISCHARGE ASSESSMENT OF GAIT SPEED AFTER HIP FRACTURE SURGERY

ABSTRACT

Background and Purposes: Hip fracture represents one of the most severe injuries in the older adults. In long-term survivors, disability is common and evaluation of walking ability may be considered as an important predictor of functional recovery. We therefore investigated if 4-m gait speed, assessed in older persons early after surgical repair of hip fracture, could predict functional recovery and subsequent development of major clinical outcomes.

Methods: This is a prospective cohort study design. We included adults aged 65+ years, admitted to a community acute care hospital with hip fracture, undergoing surgical repair. As soon as the participant was able to stand and walk, using walking aids as needed but with no person's help, the 4-m walking speed was tested as the main predictive variable. The outcome variables included: the change in the Barthel Index (BI) from pre-hospital through 1-year postoperatively as a continuous variable and two dichotomous outcomes, i.e.: 1) a decrease in BI greater than 5 points in 1 year and 2) a composite end-point, combining 5+ points BI decline, death, falls, institutionalization, and need for 24-h home assistance in 1 year.

Results: 62 participants (mean age 85 years) were enrolled and evaluated, on average 6 days (SEM=0.2) after hip fracture surgery. Compared to pre-fracture (96.3 SEM=0.9;), BI decreased 1 month after surgery (76.5 SEM=2.1) and recovered only partially at 2 (84.1 SEM=2.2) and 12 months (87.2 SEM=2.8). A pre-discharge value of the walking speed below the median (20.5 cm/sec) predicted a substantial BI reduction throughout the 12 months. Furthermore, the adjusted risk of a decline in the functional status was reduced by 5% (OR 0.95, 95% CI 0.91-0.997, p=0.038), and that of the combined outcome by 7% (OR 0.93, 95% CI 0.88-0.99, p=0.013), per each cm/sec of pre-discharge walking speed.

Discussion and Conclusion: The 4-m walking speed, measured early after surgical repair of hip fracture, has profound long-term prognostic implications. This assessment approach might prove helpful in clinical decision-making on the post-operative management of older hip fracture persons.

KEY WORDS: hip fracture, functional recovery, 4-m walking test, prognosis

INTRODUCTION

Hip fracture represents one of the most common and potentially devastating injuries in older adults. Because of a greater risk of falls and of a decreased bone mineral density, the risk of sustaining a hip fracture increases sharply with aging. ¹

The estimate mortality from hip fracture is 2-7% in the acute phase of hospitalisation, 6-12% within 30 days, and as high as 33% in the first year thereafter. In survivors the reduction of functional abilities in the year after a hip fracture can reach 15-20%, and even subjects that were fully functional prior to fracturing, after the event frequently lose their capability to live independently. The consequences of a hip fracture persist long-term: compared to persons of the same age, those with a hip fracture walk slower 2 years after the event.

The ability to walk is considered a meaningful measure of the functional capacity and overall wellbeing in several clinical conditions; in older persons, gait speed strongly predicts survival, independent of clinical variables.^{6,7} In survivors of hip fracture, the evaluation of walking ability **is** an important predictor of functional recovery and of the probability of returning home.⁸ However, an observational approach to gait assessment may be limited because of excessive subjectivity, poor reliability and floor or ceiling effects.⁹

We hypothesized that measuring the walking speed over a short distance represents a valid approach to predicting the subsequent functional evolution and clinical outcomes in adults recovering from surgery after hip fracture. To this aim, we conducted the present study to investigate if 4-m gait speed, assessed in older persons prior to discharge for hip fracture surgery, could predict the functional recovery and long-term development of major clinical outcomes, such as institutionalization or death.

METHODS

Participants and Study Protocol

All persons aged 65+ years, consecutively admitted with a hip fracture to the Orthogeriatrics Unit of Santa Maria Annunziata Community Hospital in Florence from November 2012 to April 2013, were considered eligible in a prospective cohort design study. As per general admission criterion to the Orthogeriatrics Unit, a pre-fracture Barthel Index (BI) ¹⁰ <50 (see below, Data collection) was an exclusion criterion. BI is a well-known, largely applied tool used to describe the functional status of older persons. Its items belong to the domains of self-care (feeding, grooming, bathing, dressing, bowel and bladder care, and toilet use) and mobility (ambulation, transfers, and stair climbing). Its summary score ranges from 0 (complete dependency, bedridden state) to 100 (full independence), with 5-point increases representing the minimum change in at least 1 activity. BI has good metric properties for either face-to-face, informant, or telephone ratings. ^{11,12} Other exclusion criteria were need for person's help in walking prior to admission, polytrauma, fracture due to bone metastases, critical conditions requiring admission to intensive care unit post-surgery, life

expectancy <6 months, severe cognitive impairment (as assessed from a Mini Mental State Examination, MMSE,¹³ score on admission below 18) or disruptive behaviour that might prevent functional assessment, non-surgical treatment.

Most of baseline information was gathered from hospital records on admission to the Orthogeriatrics Unit, whereas gait was assessed as soon as the participant was able to walk without person's help (see below). Telephone follow-up interviews were conducted 1, 2, and 12 months after discharge by the same examiner (SG), who remained blinded to baseline assessment; in less than 20% of the cases, when proxies had been consulted at baseline, the interview was conducted with a proxy.

The study protocol and conduction was consistent with the declaration of Helsinky. Participants were enrolled only after signing an approved informed consent form. Thus, the rights of human subjects were protected.

Data Collection

Pre-admission general health status was assessed by asking the participants to report BI, presence of 24-h home assistance, and the number of drugs taken on the 15 days prior to fracture; this last information was taken as an indirect clue to the burden of comorbidity. Proxies were consulted in the presence of person's poor cognitive status (MMSE score<18; see above). As soon as the participant was able to stand and walk, using walking aids as needed but with no person's help, gait speed (cm/sec) on a 4-m path was recorded, following the Short Physical Performance Battery Protocol. ¹⁴ To this purpose, 2 marks were placed 4-m apart in the hospital hallway, taking care they were not visible to the participant. Participants were instructed to walk at their preferred speed, as if they were going to a local shop, without pausing for resting. Timing was started when the participant began to walk after the "Go!" order was given and stopped when the end marker was crossed. The investigators provided no additional cuing once the participant began to walk. Following a brief resting, a second trail was completed. Velocity was calculated by dividing the distance walked by the time (sec) required to complete the trial; the best result out of 2 trials was chosen. A score of 0 was assigned to participants unable to perform the test.

On the 1- and 2-month telephone interviews, the BI was administered and the need for walking aid was assessed; these data were obtained again with the 12-months interview, when information on the amount and setting of rehabilitation received after discharge, new falls, need for permanent institutionalization or for 24-h home assistance was also recorded. The living status was assessed from phone interviews.

Analytic Procedures

The statistical package SPSS for Windows v. 20 was used for data management and statistical analysis. Interval variables were expressed as mean (SEM), categorical variables as percent frequencies. Descriptive statistics included Student's t test to compare the mean values of interval variables and Pearson's r coefficient to evaluate the correlation between speed and age.

Changes in BI across 4 time points (pre-fracture, 1-, 2-, and 12-month follow-up), were analysed with ANOVA for repeated measures, where Bonferroni's correction was applied to evaluate the significance of differences between values at each individual time point and baseline values. Similarly, SPSS GLM procedure was applied to assess whether the time course of BI changes, from pre-fracture to 12 months as a repeated within-subject factor, differed between the 2 groups of participants identified on the basis of the median value of walking speed. In this model, the significance of the phase x group (below or above median speed) interaction term was tested, adjusting for the following covariates: age, gender, MMSE, number of drugs on admission, type of surgery (fixation vs. arthroplasty), and days of rehabilitation post-discharge. Contrasts of individual time point values with baseline values were analysed, separately in the 2 groups, applying Bonferroni's correction.

A distinct analytic approach was also used, to verify whether 4-m walking speed as a continuous variable could predict 2 long-term outcomes. The first of these outcomes was represented by functional decline, as indicated by a decrease in BI score greater than 5 points, from pre-fracture through the 12-month follow-up. 15,16 We considered as appropriate for this study a threshold more permissive than the minimum 5-point change that the BI detects, because some degree of impairment is to be expected after hip fracture. Secondarily, a composite endpoint was created as a dichotomous variable, registering any of the followings: death, new falls, institutionalization, new need for 24-h home assistance, or long-term functional decline (i.e., more than 5 points reduction in BI). Predictors of each dichotomous outcome were identified in separate models of multivariable logistic analysis, where 4-m walking speed was entered as a continuous variable; age, gender, MMSE, number of drugs on admission, type of surgery, and days of rehabilitation post-discharge were entered as covariates and backward removed when redundant. The prediction of either dichotomous outcome was also assessed as the area under the receiver operator characteristic (ROC) curve, where the optimal combination between sensitivity and specificity cut-offs was obtained as the Youden's J statistics.

Statistical significance was set at p values <0.05.

RESULTS

A total of 62 adults, mean age 84.7 (0.9) years, range 66–94, were enrolled. Of them, 48 were women (77%). A hip prosthesis was applied in 26 participants (42%), whereas the remaining 36 cases received fixation surgery. Two other participants, potentially eligible for the study, died before enrollment and baseline evaluation; therefore, they were not included in the final study sample.

Prior to admission, all persons were able to walk without person's help. On average, pre-fracture BI was close to 100 and MMSE was only moderately reduced (Table 1). The number of drugs taken on admission was slightly above 5.

Pre-discharge, on average 6.1 (0.2) days after surgery, 47 out of 62 participants (75.8%) were able to perform the walking test, while 15 were not. In those who could walk, the range of the 4-m walk speed was 7.7 to 66.7 cm/sec and the mean speed was 28.0 (2.0) cm/sec. When persons who cannot perform the gait test and were assigned a speed of 0 were considered, the mean speed was 21.2 (2.2) cm/sec; the median value of 20.5 cm/sec divided the sample in 2 groups of 31 persons each.

Mean speed was comparable between men [23.0 (5.1) cm/sec], and women [20.7 (2.4) cm/sec, p=0.662] and was unrelated to age (r=-0.144, p=0.265). Participants receiving hip prosthesis surgery had a significantly greater speed [27.1 (3.7) cm/sec] than those undergoing fixation surgery [17.0 (2.4) cm/sec, p=0.020]. No individuals reported side effects from execution of the walking test.

Follow-Up

All baseline participants were interviewed by telephone at 1- and 2-month follow-ups, while only 57 persons (91.9%) were interviewed after 12 months, because 3 participants (5%) had died and 2 were untraceable.

Over the entire duration of the follow-up, 6/57 (11%) had received home- or office-based physiotherapy; the remaining 51 (89%) were admitted to a rehabilitation facility. Independent of the setting where physiotherapy was delivered, its average duration was 26.7 days (SEM=1.6, range 7-60).

Compared to pre-fracture, 1 month after surgery BI was markedly lower [96.3 (0.9) vs. 76.5 (2.1); p<0.001], then it increased at 2 [84.1 (2.2); p<0.001] and 12 months [87.2 (2.8); p=0.001], yet it did not completely recovery to baseline. Always compared to pre-fracture, BI was at least 5 points lower in 48/62 (77.4%), 28/62 (45.2%), and 17/57 (29.8%) participants at 1-, 2-, and 12-month follow-up, respectively.

Of the 57 participants contacted after 12 months, 38 (66.7%) had regained full walking autonomy, whereas 16 (28.1%) needed supervision and 1 (1.8%) medium assistance

with walking, and 2 (3.5%) were completely unable to walk; 28 participants (49.1%) did not need any walking aid, 12 (21.1%) reported at least 1 fall, and 10 (17.5%) were institutionalized or required 24-h home assistance. 27 (45.0%) of the 60 persons whose 12-month outcome was known reached the composite end-point of death, falls, institutionalization, new need for 24-h home assistance, or long-term functional decline.

Walking Speed, Functional Variations and Composite Outcome

Figure 1 shows changes in BI from pre-fracture through 12-month follow-up, separately for the 2 groups defined by a pre-discharge walking speed below / equal to or above the median value of 20.5 cm/sec. Participants with a greater walking speed showed a significantly lower BI reduction across time, adjusting for age, gender, MMSE, number of drugs, type of surgery, and days of rehabilitation post-discharge. At 12 months, BI recovered to baseline values only in participants with greater baseline walking speed, whereas it remained significantly lower in those whose baseline walking speed was near at or below the median.

In a multivariable logistic model, the walking speed (entered as a continuous variable) predicted BI reduction at 12 months; age, gender, MMSE, number of drugs, type of surgery, and days of physiotherapy post-discharge were all backward removed from the final model as redundant. Per each cm/sec of speed, the risk of an unfavourable functional outcome was reduced by 5%, with an adjusted OR (95% CI) of 0.95 (0.91-0.997) and p=0.038.

Similarly, the walking speed predicted the composite outcome, with an adjusted OR of 0.93 (0.88-0.99), p=0.013. MMSE was the only covariate contributing to the prediction of this outcome, with an OR (95% CI) of 0.72 (0.59-0.88), p=0.001, per each point increase; conversely, age, gender, number of drugs, type of surgery, and days of physiotherapy post-discharge were backward removed.

The area under the ROC curve was 0.73 for the dichotomous outcome of BI decline in 12-months and 0.72 for the composite outcome. A walking speed of 8 cm/sec might be proposed as a low sensitivity – high specificity cut-off for both outcomes (functional decline: 0.47 sensitivity and 0.80 specificity; composite outcome: 0.41 sensitivity and 0.82 specificity). Conversely, if a high sensitivity – low specificity cut-off is to be preferred, different values should be considered, i.e. 25 cm/sec for functional decline (sensitivity: 0.82, specificity 0.53) and 30 cm/sec for the composite outcome (sensitivity: 0.85, specificity 0.49).

DISCUSSION

This study shows that a short-distance gait speed, measured precociously after surgery in older adults with a hip fracture, can be an independent predictor of functional changes through the first year post-surgery. This predictive ability was confirmed using 2 distinct analytic approaches, where gait speed was dichotomized upon the median and functional status was expressed as an interval variable (BI) or, *viceversa*, gait speed was maintained as an interval variable and functional status was represented by BI decline beyond an arbitrary threshold of 5 points. The association with a composite endpoint combining clinically relevant events further strengthened the prognostic implications of a slow gait speed.

In agreement with previous studies, 17-21 the functional status of our participants showed a substantial decline, compared to pre-morbid conditions, soon after surgery, followed by a progressive, yet incomplete, recovery, from 1 month through the first year. Thus, in this respect, our data are purely confirmatory of the dramatic impact that a hip fracture has on the global functioning of older persons. On the other hand, we report a novel finding, that the 4-m walking speed, routinely measured as early as 6 to 7 days after surgical repair of hip fracture, has profound long-term prognostic implications. In this clinical setting, the walking ability is often investigated only from self-report, as in the BI or the Functional Independence Measure.²² To our knowledge, only 2 studies reported on measuring gait speed in acute care settings. The first was conducted on a sample of 16 participants, substantially younger than ours (77.9 vs. 84.7 years), in whom gait speed was measured on average 4.7 days after hip fracture surgery; however, the aim of the cited study was only to assess the minimum detectable change in gait velocity, whereas no prognostic implication was drawn from this measure. ²³ The second investigation was conducted on 46 adults hospitalized with a variety of diagnoses: although initially very low, gait speed improved after a brief course of physiotherapy. ²⁴ Taken together, our findings and those from the studies mentioned suggest that measuring the gait speed is feasible and safe in hospitalized persons and may provide useful information.²⁵ In particular, our data show that a short-distance test helps predicting functional evolution, expressed as BI variations, over 1 year. It is conceivable that a premorbid functional impairment has an impact of pre-discharge performance.¹⁷ However, whether a pre-discharge poor walking speed depends mostly on pre- or post-fracture conditions cannot be ascertained from our data.

In a study on 157 hip fracture persons, of whom only 57 were re-examined at follow-up, Ingemarsson et al.²⁰ reported that ability to walk 10 m within 15 sec with no need for person's help after 1 year was predicted by the Timed Up and Go Test,²⁶ but not by 10-m or 30-m walk. Beyond the differences in the performance tests and outcome measures used,

Ingemarsson's study and ours are consistent in showing that physical performance effectively predicts functional recovery long-term.

Interestingly, the MMSE score did not contribute to predicting the functional evolution over time. This might suggest that poor mental status should not represent an *a priori* reason for withholding aggressive treatment, complete pre-discharge evaluation, and post-discharge physiotherapy in older persons with hip fracture. On the other hand, it should be emphasized that MMSE was the only multivariable predictor of the composite outcome, which included death and other major clinical events: this confirms that the cognitive status is a major determinant of the overall well-being in older adults.

Attrition was negligible in this study, also compared to other reports.²⁰ This might be attributed to our choice to conduct phone interviews (therefore preventing need for transportation) and to collect proxy information: phone interviews ²⁷ and proxy information ²⁸ can allow for reliable assessment of functional abilities in older adults. We did not enroll participants with a markedly compromised pre-fracture functional status, which represents a well-known limiting factor for subsequent recovery:¹⁷ this might explain the limited long-term mortality we observed, compared to other studies.²⁹ No other strict exclusion criteria were applied and, therefore, our participants were probably representative of reasonably well-functioning older persons suffering from hip fracture; this is further supported by the general clinical characteristics of our sample, shown in Table 1. Our assessment was simple and not time-consuming, easily reproducible in the current clinical practice. Taken together, these characteristics should allow external validity of our findings, which represents a further strength of the study.

On the other hand, the small sample size clearly represents a major limitation of our study; caution should be exerted also in the view of the limited discrimination that our ROC curves offered. Moreover, most variables were obtained from routine hospital records and, therefore, their reliability and validity cannot be ascertained. Thus, our findings must be viewed as preliminary: should other, larger studies confirm our results, physical performance testing could be accepted as a safe and highly informative assessment, applicable in older adults early after surgical repair of hip fracture. Besides its purely prognostic implications, this assessment approach might provide helpful also in clinical decision making on the post-operative management.

CONCLUSIONS

Short-distance gait speed, assessed pre-discharge in older persons after hip fracture surgery, predict long-term functional changes and major clinical outcomes, independent of

other factors. We therefore recommend the application of this simple assessment in older adults recovering from hip fracture. This assessment approach might prove helpful in clinical decision-making on the post-operative management of older persons with hip fracture.

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Figure 1. Change in the Barthel Index from pre-fracture (baseline, BL) though 1-year follow-up according to pre-discharge gait speed, dichotomized at the median value of 20.5 cm/sec. Phase x group interaction: p=0.003. In participants with gait speed above the median: 1-month and 2-month follow-ups vs. baseline p<0.001; 12-month follow-up vs. baseline p=0.074. In participants with gait speed at or below the median: 1-month and 2-month follow-ups vs. baseline p<0.001; 12-month follow-up vs. baseline p=0.005.

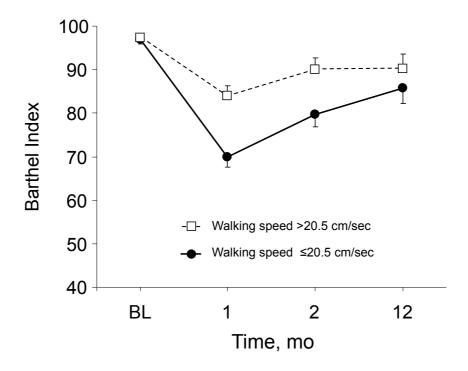


Table 1. Basal characteristics of participants. Values are given as means (SEM)

Variable	Mean (SEM)	Range
Age, y	84.7 (0.9)	66–94
Gender, male/female	14/48	
Kind of surgery, fixation/prosthesis	36/26	
Pre-fracture Barthel Index	96.3 (0.9)	65-100
Mini Mental State Examination	23.8 (0.7)	12.8-30
Number of drugs	5.4 (0.2)	3-10
Walking speed, cm/sec	21.2 (2.2)	0-66.7