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A Simple Gait-Stabilizing Device Reduces Outdoor Falls and Nonserious Injurious Falls in Fall-Prone Older People During the Winter

Fergus Eoin McKiernan, MD

OBJECTIVES: To determine whether Yaktrax Walker (YW), a nonmedical gait-stabilizing device, prevents outdoor falls and injurious falls in fall-prone older people during the winter.

DESIGN: Prospective, randomized, interventional trial.

SETTING: Community-based, northern United States, winter, outdoors.

PARTICIPANTS: Ambulatory, community-dwelling, fall-prone people aged 65 and older.

INTERVENTION: Participants were randomized to wear YW or their usual winter footwear (UWF) outdoors during the winter of 2003/2004.

MEASUREMENTS: The number of indoor and outdoor slips, falls, and injurious falls was recorded daily in a fall diary. Winter footwear satisfaction survey was completed after study completion.

RESULTS: One hundred nine subjects completed 10,724 diary days. Mean age was 74.2. There were 93 indoor slips, 13 indoor falls, 714 outdoor slips, and 62 outdoor falls. The tendency for both groups to slip/fall indoors was comparable. The relative risk (RR) of outdoor slip for YW was 0.50 ($P<.04$) for all diary days and 0.61 ($P=.14$) when only days walked on snow and ice was the exposure variable. The RR of outdoor fall for YW was 0.42 ($P<.03$) when only days walked on snow and ice was the exposure variable. RR of injurious falls per day walked on snow and ice for YW was 0.13 ($P<.02$). Twelve of 19 outdoor falls occurred when YW subjects were not wearing their assigned device. No serious injury or fracture occurred in either group. The number needed to treat for the YW to prevent one nonserious injurious fall in one winter was six.

CONCLUSION: YW may reduce the risk of outdoor winter falls, and of nonserious injurious falls, in older community-dwelling people with a history of previous falls. J Am Geriatr Soc 53:943–947, 2005.

From the Center for Bone Diseases, Marshfield Clinic, Marshfield, Wisconsin.

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Address correspondence to Fergus Eoin McKiernan, MD, Center for Bone Diseases, Marshfield Clinic, 1000 North Oak Avenue, Marshfield, WI 54449. E-mail: mckiernan.fergus@marshfieldclinic.org

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Falling is the leading cause of accidental death and the sixth leading cause of all deaths in older people (aged ≥65) in the United States.[1,2] Approximately 20% of falls in older people require emergency medical attention, and 30% to 50% of these result in hospitalization. Five percent to 10% of falls in older people result in serious soft tissue injury, 3% to 5% in skeletal fracture, and 1% to 2% in hip fracture.[1–4] Conversely, a fall precedes 90% of hip fractures[5] and 25% to 40% of vertebral compression fractures.[6] If a person has low bone mineral density, the risk of hip fracture resulting from a fall is tripled.[7] The personal, family, and societal consequences of fractures in older people, particularly hip fracture, can be devastating. Therefore, fall prevention is an important facet of any osteoporotic fracture reduction scheme.

The predisposition to fall represents a complex interplay of environmental conditions, visual acuity, neuromuscular agility, and strength that iatrogenic factors such as polypharmacy can aggravate. In dry environmental conditions, fall-prevention strategies have resulted in fewer fractures.[8] Similar trials in hazardous winter conditions have not been published. Falls may occur more frequently in the winter in northern latitudes because of more hazardous environmental conditions and suboptimal vitamin D status.[9,10] Improving gait stability in these conditions should result in fewer falls and injuries. Recently, the American and British Geriatric Societies and American Academy of Orthopedic Surgeon's Panel on Falls Prevention published guidelines for the prevention of falls in older persons.[4] One of 12 questions that this panel identified as high priority for future research was "What is the safest footwear for people who have fallen or are at risk for falling?" The purpose of this study is to determine whether a simple, nonmedical device designed to improve gait stability in hazardous winter conditions (Yaktrax Walker (YW), Figure 1)[11] reduces outdoor slips and falls or results in fewer injurious falls in fall-prone, community-dwelling, ambulatory older people.

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Figure 1. The Yaktrax Walker.

METHODS

The Marshfield Clinic Research Foundation institutional review board approved this study protocol. The prospective study was conducted at Marshfield Clinic, Marshfield, Wisconsin (latitude 44.49175°N) and Marshfield Clinic-Lakeland Center, Minocqua, Wisconsin (latitude 45.82466°N) during the winter of 2003/2004. A fall registry was constructed from a database of community-dwelling older people who had fallen at least once during the previous year and had been evaluated in clinic urgent care or primary care centers or in either of two affiliated hospital emergency departments. Participants were recruited from the fall registry using a single direct mailing and in response to a single announcement in local print media. Respondents were initially screened by telephone interview to confirm that they were aged 65 and older, community dwelling, and independently ambulatory and had sustained at least one (indoor or outdoor) fall within the preceding year. Falls were defined as any unintentional assumption of the nonupright position on the ground or any other intervening surface. Slips were defined as any unintentional deviation from the upright position that would have resulted in a fall in the absence of an immediate corrective action. Candidates had to be willing to accept assignment to the intervention (YW) or nonintervention (usual winter footwear (UWF)) group and not to enroll with the a priori intention of violating the assignment. YW (Figure 1) is a proprietary injection-molded thermal plastic elastomer netting sized to conform to the external length and width of a boot or shoe. High strength coils encase the netting in a configuration intended to provide multidirectional gait stability under outdoor winter conditions.[11]

Study candidates had to be capable of applying the YW correctly and to discern appropriate outdoor conditions for their use according to manufacturer's recommendations. Candidates had to be able and willing to maintain a fall diary and accurately record all indoor and outdoor slips and falls throughout the study duration, the surface upon which the fall occurred, footwear worn at the time of the slip or fall (including use of the YW or similar device), and any fall-related injuries. Candidates who satisfactorily met all inclusion criteria were randomized using independent numerical assignment to wear YW under appropriate environmental conditions or their UWF outdoors during the winter of 2003/2004. Yaktrax, Inc. provided each YW study subject with one pair of appropriately sized YWs and agreed to replace that pair in the event of device failure. Subjects were strictly counseled never to wear YW indoors or on smooth outdoor nonice surfaces. Subjects were allowed to reside outside of the immediate geographic region for up to 1 month during the study duration without disqualification. All subjects completed a footwear satisfaction survey after study termination. After receipt of all completed fall diaries and footwear satisfaction surveys, each study subject was nominally compensated ($20) for the inconveniences incurred because of study participation. Injurious falls were rated as mild (no medical attention), moderate (medical attention), or serious (hospitalization). Indoor slip and fall rates served as the control to compare the tendency to fall between groups. Subjects whose indoor slip or fall rate exceeded the group mean by more than 3 standard deviations were considered outliers and were excluded from final analysis. Analysis was on an intention-to-treat basis. Chi-square, Negative Binomial Model, and Fisher exact tests using SAS software (SAS Institute, Inc., Cary, NC) were used to test the difference of outcomes between intervention and nonintervention groups. Yaktrax, Inc. had no involvement in the conception, design, implementation, or analysis of the study and had no involvement in the preparation or review of the manuscript. Neither the author nor his institution has any direct or indirect financial interest in Yaktrax, Inc. or received any compensation from Yaktrax, Inc. or any other commercial interest in conducting this research.

RESULTS

One hundred thirteen subjects met inclusion criteria and were randomized. Four randomized subjects were excluded from the final data analysis; two UWF subjects met the test for exclusion as outliers, one YW subject withdrew consent after randomization, and one UWF subject completed only 10 diary days. The final study population consisted of 109 older people, of whom 65 (60%) were female and 44 (40%) male. Mean subject age was 74.2 (range 65–96). Ninety-five percent of all fall diaries and footwear satisfaction surveys were completed and returned for analysis. Of those assigned to wear YW, 78% confirmed that they had used the YW as their primary winter footwear during the course of the study under appropriate environmental conditions. Of those assigned to UWF, 19% admitted that they had used the YW or a similar gait-stabilizing device during the course of the study. The difference in use of the YW between groups was highly significant ($P<.001$). Throughout 10,724 observation-days, there were a total of 93 indoor slips, 13 indoor falls, 714 outdoor slips, and 62 outdoor falls. Ice was the most common surface involved in outdoor slips and falls in both groups. Boots (with or without the YW) were the most commonly worn footwear at the time of outdoor slips and falls in both groups. Age, sex, and footwear assignment did not influence indoor slip and fall rates. Compared with the UWF group, the relative risks (RRs) for indoor slips and indoor falls in the YW group were 1.47 ($P=.45$) and 1.19 ($P=.78$), respectively, indicating that the tendency for both

Table 1. Indoor Slip and Fall Rates and Relative Risks (RR) in Yaktrax Walker Group Compared with Usual Winter Footwear Group

Group	Diary Days n	Indoor Slips n (RR)	Indoor Falls n (RR)
Yaktrax Walker (n = 55)	5,358	55 (1.47)*	7 (1.19)†
Usual winter footwear (n = 54)	5,366	38 (1.0)	6 (1.0)

* Wald 95% confidence interval (CI) = 0.55–3.87, $P > .44$.
† Wald 95% CI = 0.39–3.48, $P > .77$.

groups to slip or fall indoors was comparable (Table 1). Age did not influence outdoor slip and fall rates. Men slipped and fell more often than women outdoors, with RRs of 1.5 ($P < .02$) and 4.0 ($P < .001$), respectively. Compared with the UWF group, the RR of outdoor slips in the YW group was 0.50 ($P < .04$) when all diary days was used as the exposure variable (Table 2). When the exposure variable was only those days walked on snow and ice, the RR of outdoor slips in the YW group was 0.61 ($P = .14$) (Table 3). The RRs of outdoor falls in the YW group were 0.45 ($P < .02$) using all diary days as the exposure variable and 0.42 ($P < .03$) when only days walked on snow and ice, was the exposure variable. Approximately one-third of all outdoor slips and two-thirds of all outdoor falls recorded in the YW group occurred when subjects were not wearing their assigned device (Table 4). Falls resulted in 10 injuries (8 mild, 2 moderate) in the UFW group and one mild injury in YW group. No serious injury or fracture occurred in either group. The RR of a nonserious injurious fall over the course of the winter in subjects assigned to wear the YW was 0.10 ($P < .02$). The RR of a nonserious injurious fall per day walked on snow and ice for YW was 0.13 ($P < .02$). The number of persons that had to be assigned to wear the YW (number needed to treat (NNT)) to prevent one nonserious injurious fall per winter was six. The NNTs to prevent one wintertime outdoor slip or outdoor fall were 1 and 3, respectively (Table 3).

Eighty percent of the YW group but only 40% of the UWF group felt strongly that they planned to use their assigned winter footwear the following winter ($P < .001$). Sixty-three percent of the YW group but only 26% of the UWF group indicated that they got outdoors more often because of their assigned footwear ($P < .001$). Seventy-four percent of the YW group but only 18% of the UWF group strongly agreed that they felt very secure while walking outdoors during the winter ($P < .001$). Both groups agreed that applying their assigned footwear was easy, although the difference favored YW (80% vs 54%; $P < .01$). There were three device failures requiring device replacement, and no device failure contributed to a slip, fall, or injury.

CONCLUSION

These results indicate that a simple gait-stabilizing device (YW) can prevent outdoor falls and nonserious injurious falls in fall-prone, ambulatory older people when carefully applied and worn under appropriate environmental conditions. Strengths of this study include the unusually high degree of participant compliance and follow-up, the representative outdoor winter conditions during the course of the study, and the community-based nature of the study population. The reported magnitude of outdoor fall reduction in this study is likely conservative because the majority of outdoor falls in the YW group occurred when subjects were not wearing their assigned device. Furthermore, a substantial number of subjects assigned to the UWF group indicated that they had used YWs or similar gait-stabilizing devices during the course of the study. In this latter group, seven outdoor slips in five subjects were recorded, but there were no outdoor falls. This unintended crossover likely attenuated the measured beneficial effect of the device. The absolute magnitude of fall reduction and thus the NNT to prevent falls and injurious falls will vary with the propensity to fall in the population using the device. This study population was enriched with fall-prone older people, so similar benefits may not be applicable to a less-fall-prone population. Conversely, a frailer or older population might not find application of the YW to be as straightforward. Misapplication of the device or failure to recognize device failure might increase the risk of fall.

There were no serious injurious falls or fractures in this study. It has been estimated that, each year, 5% of older people in Wisconsin experience a fall that results in hospi-

Table 2. Outdoor Slip, Fall, and Injurious Fall Rates and Relative Risks (RRs) in Yaktrax Walker Group Compared with Usual Winter Footwear Group Using All Diary Days as the Exposure Variable

Group	Total Diary Days n	Total Outdoor Slip n (RR)	Total Outdoor Fall n (RR)	Total Outdoor Injurious Fall n (RR)
Yaktrax Walker (n = 55)	5,358	229 (0.50)*	19 (0.45)†	1 (0.1)‡
Usual winter footwear (n = 54)	5,366	485 (1.0)	43 (1.0)	10 (1.0)

* Wald 95% confidence interval (CI) = 0.26–0.96, $P < .04$.
† Wald 95% CI = 0.23–0.85, $P < .02$.
‡ Approximate 95% CI = 0.02–0.53, $P < .02$.

Table 3. Outdoor Slip, Fall, and Injurious Fall Rates and Relative Risks (RR) in Yaktrax Walker Group Compared with Usual Winter Footwear Group Using Only Days Walked on Snow and Ice as the Exposure Variable

Group	Total Diary Days n	Total Outdoor Slips* RR	Total Outdoor Falls† RR	Total Outdoor Injurious Falls‡ RR
Yaktrax Walker (n = 55)	3,634	229 (0.61)§	19 (0.42)‖	1 (0.13)¶
Usual winter footwear (n = 54)	4,274	485 (1.0)	43 (1.0)	10 (1.0)

Number of persons that must wear Yaktrax Walker on snow and ice to prevent one slip, fall, or nonserious injurious fall over the course of one winter (number needed to treat (NNT)):
* NNT = 1 (95% confidence interval (CI) = 1–1),
† NNT = 3 (95% CI = 1–11),
‡ NNT = 6 (95% CI = 3–13).
§ Wald 95% CI = 0.33–1.17, $P > .14$.
‖ Wald 95% CI = 0.26–0.92, $P < .03$.
¶ Approximately 95% CI = 0.03–0.66, $P < .02$.

talization.[12] One-quarter of these falls occurred during January, February, and March, so 1.4 fall-related hospitalizations might have been anticipated during the course of the current study. Considering the significant reduction of nonserious injurious falls in the YW group, the current study was probably underpowered to detect a significant difference in falls that result in hospitalization between the intervention and nonintervention arms. The average estimated medical cost for fall-related emergency department evaluation in older people is $9,400[13] and for fall-related hospitalization is $19,440.[14] The manufacturer's current suggested retail price for the YW is less than $20 per pair.[11] Given a NNT of six, these data suggest that it may cost less than $120 to prevent one nonserious injurious fall in a population of fall-prone older people during one winter. From 2000 to 2040, the number of people aged 65 and older is projected to increase from 35.1 million to 86.7 million.[15] In 1999, Medicare spent more than $8 billion on the treatment of injuries to older people (6% of all Medicare fee-for-service claims), and fractures accounted for two-thirds of this cost.[16]

Falling and fall-related consequences will constitute an increasing burden on the healthcare system. Fall-reduction strategies should result in fewer serious injuries, fractures, and fatalities and an increase in healthcare savings. Targeting the most appropriate fall-reduction intervention to the right population should yield the best rate of therapeutic return. Under appropriate environmental conditions, YW appears to be an inexpensive means of preventing falls and nonserious injurious falls in fall-prone, ambulatory, community-dwelling older people during the winter.

Table 4. Status of Yaktrax Walker at the Time of Outdoor Slip and Fall

Wearing Yaktrax Walker	Total Outdoor Slips (n = 229) n	Total Outdoor Falls (n = 19) n
Yes	145	7
No	80	12
Uncertain	4	0

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REFERENCES

1. Tinnetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. N Engl J Med 1988;319:1701–1707.
2. Colon-Emeric CS. Falls in older adults: Assessment and intervention in primary care. Hosp Physician 2002;4:55–66.
3. Alexander BH, Rivara FP, Wolf ME. The cost and frequency of hospitalization for fall related injuries in older adults. Am J Public Health 1992;82: 1020–1023.
4. American Geriatric Society British Geriatric Society, and American Academy of Orthopedic Surgeons Panel on Falls Prevention. Guideline for the Prevention of Falls in Older Persons. J Am Geriatr Soc 2001;49:664–672.
5. Schwartz AV, Capezuti E, Grisso JA. Falls as risk factors for fractures. In: Marcus R, Feldman D, Kelsey J, eds. Osteoporosis, 2nd Ed. San Diego, CA: Academic Press, 2001, pp 795–807.
6. Cooper C, Atkinson EJ, O'Fallon WM et al. Incidence of clinically diagnosed vertebral fractures: A population-based study in Rochester, Minnesota, 1985–89. J Bone Min Res 1992;7:221–227.
7. Schott AM, Cormier C, Hans D et al. How hip and whole-body bone mineral density predict hip fracture in elderly women. The EPIDOS Prospective Study. Osteoporos Int 1998;8:247–254.
8. Gillespie LD, Gillespie WJ, Robertson MC et al. Interventions for preventing falls in elderly people. Cochrane Database Syst Rev 2003;(4):CD000340.
9. State Injury Profile for Wisconsin [on-line]. Available at www.cdc.gov/ncipc/StateProfiles/sip_wi.pdf Accessed January 4, 2005.

10. Pasco JA, Henry MJ, Kotowicz MA et al. Seasonal periodicity of serum vitamin D and parathyroid hormone, bone resorption, and fractures: The Geelong Osteoporosis Study. J Bone Miner Res 2004;19:752–758.
11. Yaktrax [on-line]. Available at www.yaktrax.com Accessed January 4, 2005.
12. Guse CE, Porinski R. Risk factors associated with hospitalization for unintentional falls. Wisconsin hospitalization discharge data for patients aged 65 and over. Wisconsin Med J 2003;102:37–42.
13. Public Policy Institute. Falls Among Older Persons and the Role of the Home: An Analysis of Cost, Incidence, and Potential Savings from Home Modification [on-line]. Available at http://research.aarp.org/il/ib56_falls.pdf Accessed January 4, 2005.
14. Rizzo JA, Friedkin R, Williams CS. Health care utilization and costs in a Medicare population by fall status. Med Care 1998;36:1174–1188.
15. U.S. Bureau of the Census. Population Projections Program, Population Division. Projected Population of the United States, by Age and Sex: 2000 to 2050 [on-line]. Washington, DC. Available at www.census.gov/ipc/www/usinterimproj/natprojtab02a.pdf Accessed January 4, 2005.
16. Bishop CE, Gilden D, Blom J et al. Medicare spending for injured elders: Are there opportunities for savings? Health Aff (Milwood) 2002;21:215–223.