Smartphone-Based Self-Assessment of Objective Functional Impairment (6-Minute Walking Test) in Patients Undergoing Epidural Steroid Injection

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Abstract: Epidural steroid injection (ESI) represents a popular treatment option in patients with lumbar degenerative disc disease (DDD). The main objective of the article was to determine whether the 6-minute walking test (6WT) could assist in the discrimination between ESI responders and nonresponders. We used a validated 6WT smartphone application to assess self-measured objective functional impairment (OFI) in 3 patients with DDD undergoing ESI. Patient-reported outcome measures (PROMs), including the Core Outcome Measures Index and the Oswestry Disability Index, were obtained at baseline and at the 3-, 7-, and 28-day follow-up. Descriptive analyses were used to compare PROMs with OFI over time. Two patients responded well to the ESI, illustrated by clinically meaningful improvements in PROMs. This improvement was accompanied by a substantial increase in the 6WT distance (case I: 358 m vs. 517 m and case II: 296 m vs. 625 m). One patient reported only moderate improvement in leg pain and conflicting results in the other PROMs. The 6WT demonstrated a persistent OFI (487 m vs. 488 m). This patient was considered a nonresponder and underwent surgical treatment. This case series illustrates the feasibility of the smartphone-based 6WT as a tool to assess OFI in patients undergoing ESI for lumbar DDD.

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Case Report

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Smartphone-Based Self-Assessment of Objective Functional Impairment (6-Minute Walking Test) in Patients Undergoing Epidural Steroid Injection

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Epidural steroid injection (ESI) represents a popular treatment option in patients with lumbar degenerative disc disease (DDD). The main objective of the article was to determine whether the 6-minute walking test (6WT) could assist in the discrimination between ESI responders and nonresponders. We used a validated 6WT smartphone application to assess self-measured objective functional impairment (OFI) in 3 patients with DDD undergoing ESI. Patient-reported outcome measures (PROMs), including the Core Outcome Measures Index and the Oswestry Disability Index, were obtained at baseline and at the 3-, 7-, and 28-day follow-up. Descriptive analyses were used to compare PROMs with OFI over time. Two patients responded well to the ESI, illustrated by clinically meaningful improvements in PROMs. This improvement was accompanied by a substantial increase in the 6WT distance (case I: 358 m vs. 517 m and case II: 296 m vs. 625 m). One patient reported only moderate improvement in leg pain and conflicting results in the other PROMs. The 6WT demonstrated a persistent OFI (487 m vs. 488 m). This patient was considered a nonresponder and underwent surgical treatment. This case series illustrates the feasibility of the smartphone-based 6WT as a tool to assess OFI in patients undergoing ESI for lumbar DDD.

Keywords: Lumbar disc herniation, Objective functional impairment, Epidural steroid injection

INTRODUCTION

A thorough evaluation of functional impairment is essential to critically assess outcome and treatment efficacy in patients undergoing surgical or conservative treatment for lumbar degenerative disc diseases (DDDs). Traditionally, patient-reported outcome measures (PROMs) in the form of questionnaires are deployed to assess a patient's subjective well-being, pain level, and impairment. More recently, several measures of objective functional impairment (OFI) have been described in the literature with the aim to complement PROMs by contributing an objective outcome dimension to the comprehensive patient evaluation.[2]

Despite the growing number of publications in this field, to date there is no shared "gold standard" for the objective assessment of patients suffering from DDD.[1] The majority of described objective measures, for example, the motorized-treadmill-test or the self-paced walk test, require considerable resources including specific equipment, trained personal and time commitment.[2,3] Few objective outcome measures exist that can be self-performed by the patient without supervision. The 6-minute walking test (6WT) was identified as a promising tool in a recent systematic review of objective outcomes in spinal surgery.[1] For this purpose, a 6WT smartphone application (app) was de-

veloped to be utilized by spine patients in their home environment.[4]

To date, there have been no reports on the use of the 6WT as an objective, self-measured functional assessment in patients undergoing lumbar interlaminar or transforaminal epidural steroid injection (ESI) for DDD. ESI represents a frequently performed nonsurgical management option in DDD even though its therapeutic benefits are debated and the diagnostic information gained from the procedure remains controversial.[5-7] Whether or not a patient experienced a positive response to ESI remains difficult to determine in some settings. The 6WT may prove useful in identifying ESI responders and nonresponders. This case series presents the first experience gained while using the 6WT app in patients undergoing ESI for lumbar DDD. We compare changes in the 6WT with established PROMs and discuss the added diagnostic benefit of the 6WT.

MATERIALS AND METHODS

1. Patient Identification

We recruited 3 consecutive patients (>18 years) scheduled to undergo transforaminal or interlaminar ESI due to lumbar DDD at the Kantonsspital St. Gallen, Switzerland, between August and September 2019. There were no drop-outs and none of the 3 patients failed to complete the follow-up. All patients were treated according to local clinical standards.

2. Subjective Outcome Assessment

Patient was asked to fill out PROM questionnaires, including the core outcome measures index (COMI) back[8] and the Oswestry Disability Index (ODI)[9] before the intervention and at the 28-day follow-up. Participants additionally documented their leg pain on a numeric rating scale (NRS; range from 0 [no pain] to 10 [maximum pain]) for 7 consecutive days following the intervention using a pain diary. At the 28-day follow-up, the treating neurosurgeons evaluated the overall treatment response during a face-to-face outpatient consultation.

3. Assessment of OFI

Previously known to assess cardiovascular health, the 6WT determines restrictions in maximum walking capacity. The test's main result is a function of the maximum distance in meters (m) a person can walk in 6 minutes (the 6-minute walking distance, 6WD). In patients with lumbar DDD, pain and functional restrictions frequently lower the maximum 6WD, as patients might ambulate slower or have to take breaks in order to alleviate symptoms of leg and back pain. To assess OFI, patients were instructed to use the recently developed free 6WT smartphone app in their home environment. This spine-specific 6WT app was demonstrated to be highly reliable in settings that resemble a patient's home environment.[4]

At first consultation, the 6WT app was downloaded from the Google Play Store or Apple Store (link to the 6WT app: see Supplementary material) onto the patient's smartphone (Fig. 1). Patients received detailed instructions by their treating neurosurgeon prior to using the app. They consented that the app would measure the 6WD by accessing their smartphone's global positioning system coordinates. Patients were instructed to select a sufficiently long (around 700 m), flat and level environment within their neighborhood, since app-based 6WD measurements had optimal reliability under those circumstances.[4] Patients were then instructed to perform the 6WT twice at 4-time

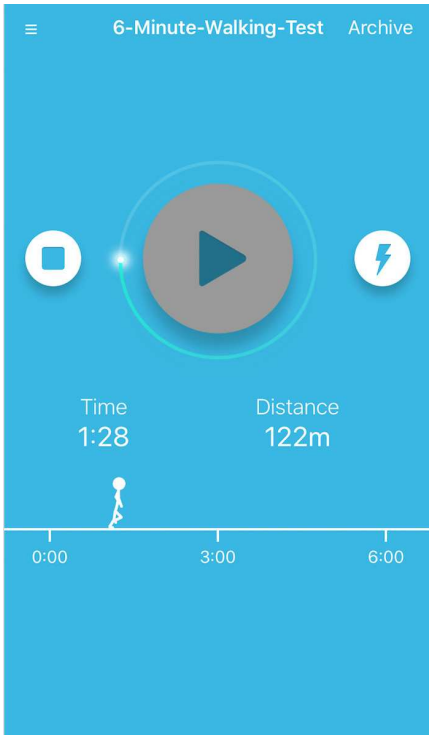

Fig. 1. The 6-minute walking test smartphone application. By pressing the "Play" button, the application starts measuring a patient's distance walked within 6 minutes as main outcome using GPS (global positioning system) coordinates. Both distance and time are displayed on the screen while walking. In this example, the measurement is at 1:28 minutes and 122 m and still ongoing. After 6 minutes, the measurement stops automatically. By pressing the "Archive" button on the upper right corner, completed measurements are captured with a date and time stamp.

points: (1) prior to the ESI, (2) at 3 days, (3) at 7 days, and (4) at 28 days after the intervention. The mean 6WD of both measurements for each time point was used.

4. Injection Technique

For transforaminal ESI, a 25-gauge spinal needle was used to advance toward the targeted intervertebral foramen under anteriorposterior fluoroscopic imaging. When the position lateral to the inferior margin of the targeted pedicle was reached, iodinated contrast (Iopamiro, Bracco Suisse SA, Geneva, Switzerland) was instilled under real-time fluoroscopy. A mixture of 2 mL of bupivacaine (0.75%) and 1-mL mephameson (4 mg/mL) was used for ESI, in accordance with our institutional policy.[10] The patients were discharged on the same day.

For interlaminar ESI, patients were positioned prone with mild lumbar kyphosis to increase the interlaminar space. Fluoroscopic anteriorposterior imaging was used to identify the targeted vertebral level. First, local anesthesia with rapidocain (1%) was applied. Then, a 17-G spinal needle was advanced parallel to the image trajectory until encountering loss of resistance after penetrating the ligamentum flavum under continuous saline injection. Subsequently, iodinated contrast (Iopamiro) was injected to confirm epidural placement. Once optimal contrast distribution was seen, 2-mg diprophos and 5-mL lidocain (1%) were instilled into the epidural space. Following the procedure, patients routinely underwent monitoring for 2 hours before being discharged.

5. Statistical Analysis

Due to the small sample size, no statistical tests were applied but descriptive analyses were chosen. OFI by the 6WD was interpreted according to age-specific normal population reference values (31–50 years: 624 ± 83 m [95% confidence interval, 604–643; n = 70]; 51–70 years: 573 ± 92 m [556–590, n = 120]; > 71 years: 438 ± 130 m [381–496, n = 22]; unpublished data). Change in the PROMs was considered clinically meaningful if it corresponded to at least the minimum clinically important difference (MCID) of each outcome measure, namely 1.7 on the NRS for leg pain, 14.3 on the ODI[11] and 1.20 for the COMI.[12]

6. Ethical Considerations

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The collection and publication of data were permitted by the local ethic committee (Kantonale Ethikkommission, EKOS - 2019-01209). All patients provided written informed consent prior to the initiation of the data collection.

CASE REPORTS

Three consecutive cases are presented to illustrate agreement between PROMs and OFI in treatment responders and nonresponders.

1. Case 1

A 54-year-old otherwise healthy male presented to our emergency clinic with a 2-week history of sudden onset of right-sided pain on the dorsolateral thigh and calf (NRS, 8/10; ODI, 18/100; COMI, 7.4/10). He additionally reported numbness in his lateral thigh and calf. The pain was aggravated while walking and standing, and with 296 m his baseline 6WD was well-

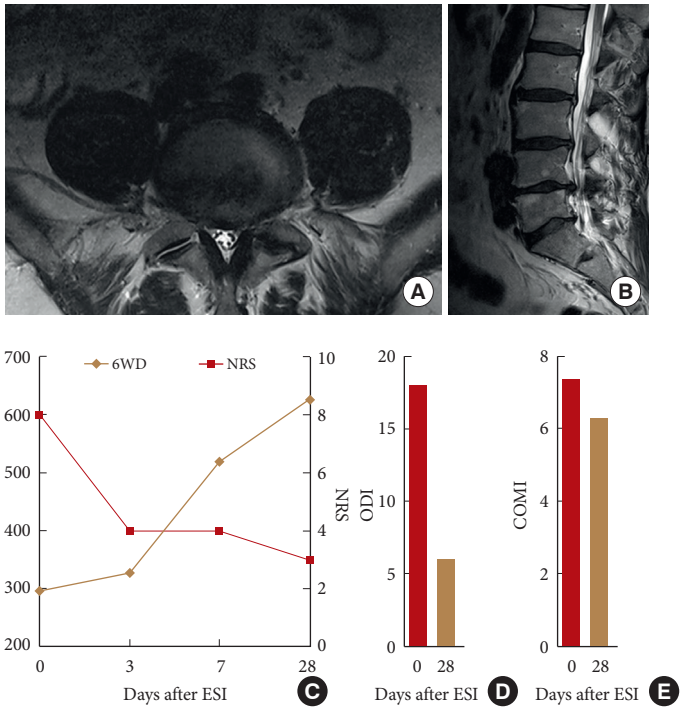

Fig. 2. (A, B) Axial and sagittal magnetic resonance images of case 1. (C) The 6-minute walking distance (6WD) in meters before and after the lumbar epidural steroid injection (ESI) is displayed on the left *x*-axis. Changes in the numeric rating scale (NRS) are plotted on the right *x*-axis. (D, E) The core outcome measures index back (COMI) and the Oswestry Disability Index (ODI) are shown before the ESI and at the 4-week follow-up.

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below the age-adjusted norm. Physical examination was unremarkable except for hypesthesia along the L5 dermatome. Lumbar spine magnetic resonance imaging (MRI) revealed a broad-based L4/5 disc protrusion with consecutive L5 nerve compression (Fig. 2A, B). After 4 weeks of conservative treatment without sufficient pain relief, the patient underwent a right-sided L5 transforaminal ESI.

At the 4-week follow-up, the patient described a clinically meaningful relief of his leg pain (NRS, 3/10; Fig. 2C) and subjective back-related disability measure (ODI, 6/100; Fig. 2E). Interestingly, the COMI decreased only by 1.1 points, thus failing to reach a clinically meaningful difference (Fig. 2D). However, the patient had been able to discontinue using opioids and had returned to work. His self-reported improvement at this time was reflected by a normalization of his 6WD (625 m; Fig. 2C).

2. Case 2

A 62-year-old male presented at our outpatient clinic with a 4-month history of progressive neurogenic claudication (NRS leg pain, 7/10; ODI, 20/100; COMI, 7/10). He additionally complained of diffuse weakness in his right leg. Physical examination showed a mild paresis of his right iliopsoas muscle (4/5). Lumbar MRI revealed a discoligamentous lumbar spinal stenosis at L3/4 with predominantly right-sided L4 nerve compression (Fig. 3A, B). The patient was not taking any pain medication but felt limited in his activities of daily living due to the exercise-dependent pain and weakness in his right leg. Correspondingly the 6WD (358 m) was well-below the age-specific norm. The patient underwent an interlaminar ESI at L3/4.

At the 4-week follow-up, the patient reported a complete remission of his neurogenic claudication and muscle weakness. This was reflected by an increase in 6WD to 517 m 4 weeks after ESI, approaching his age-specific normal population range (Fig. 3C). Additionally, we observed a parallel, clinically meaningful decrease in both the ODI (7/100) and COMI (0.2/10) (Fig. 3D, E).

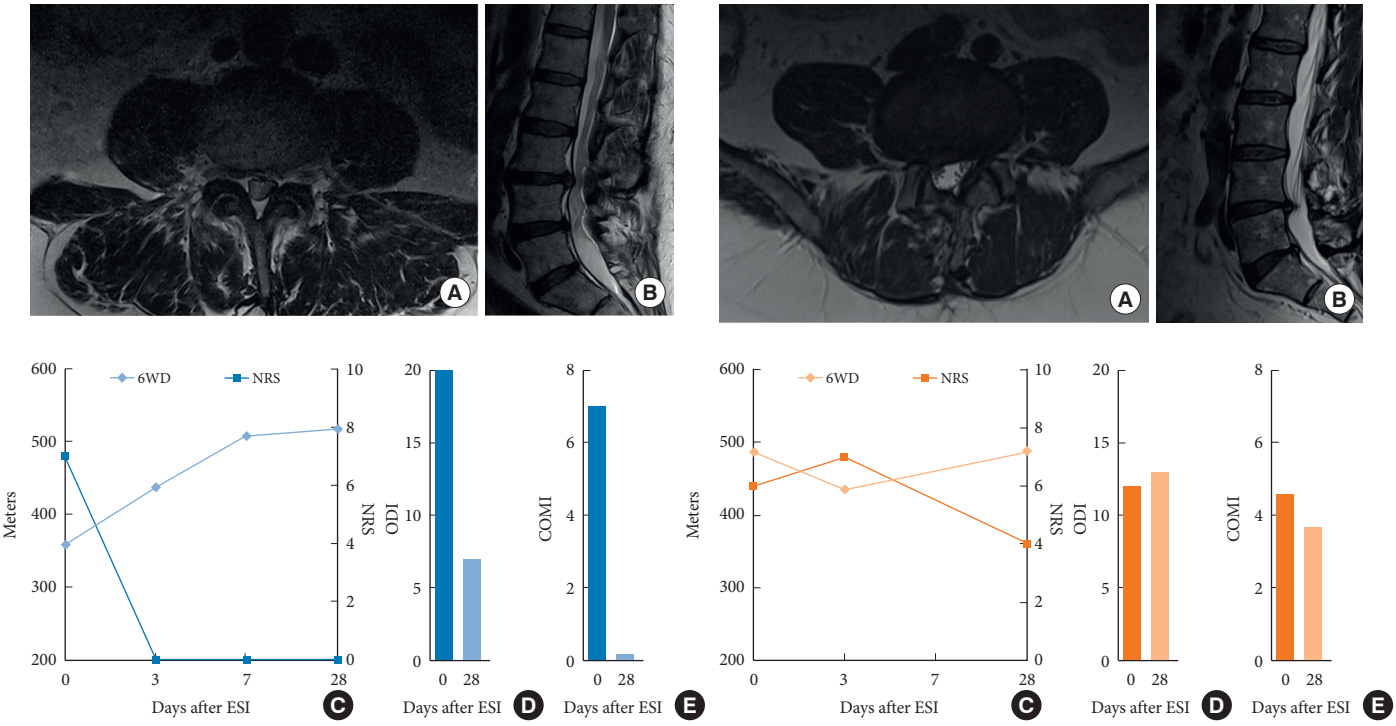

Fig. 3. (A, B) Axial and sagittal magnetic resonance images of case 2. (C) The 6-minute walking distance (6WD) in meters before and after the lumbar epidural steroid injection (ESI) is displayed on the left *x*-axis. Changes in the numeric rating scale (NRS) are plotted on the right *x*-axis. (D, E) The core outcome measures index back (COMI) and the Oswestry Disability Index (ODI) are shown before the ESI and at the 4-week follow-up.

Fig. 4. (A, B) Axial and sagittal magnetic resonance images of case 3. (C) The 6-minute walking distance (6WD) in meters before and after the lumbar epidural steroid injection (ESI) is displayed on the left *x*-axis. Changes in the numeric rating scale (NRS) are plotted on the right *x*-axis. (D, E) The core outcome measures index back (COMI) and the Oswestry Disability Index (ODI) are shown before the ESI and at the 4-week follow-up.

3. Case 3

A 56-year-old male presented to our outpatient clinic with progressive right-sided lumbar pain radiating to the lateral thigh and malleolus lateralis (NRS, 6/10; ODI, 12/100; COMI, 5.7/10). The leg pain had started 2 weeks prior without preceding trauma. His pain was aggravated by standing and walking; his mean 6WD was below his normal population reference (487 m). The patient had undergone right-sided L4/5 sequestrectomy due to disc herniation 13 months prior and had been pain free until this new pain episode started. The physical examination was unremarkable. Lumbar spine MRI showed a right-sided L4/5 recurrent disc herniation compromising the L5 nerve in the intervertebral recess (Fig. 4A, B). As his symptoms worsened despite conservative treatment, he received a right L5 transforaminal ESI.

The patient reported a moderate pain relief from to NRS 4 leg pain (just surpassing the MCID) at 4 weeks (Fig. 4C). Analysis of the 6WD over time showed a slight decrease immediately after the intervention and no substantial improvement at the 28-day follow-up (Fig. 4C). PROMs provided conflicting results: while his ODI increased during follow-up (13/100; Fig. 4E), his COMI showed minor, yet not clinically meaningful improvement (4.6/10; Fig. 4D). The patient was not satisfied with his clinical situation and functional level despite the ESI (= non-responder). He signed up for L4/5 sequestrectomy shortly after.

DISCUSSION

This case series represents the first account on the use of the 6WT smartphone app as a tool to assess OFI before and after ESI in patients with DDD. It provides preliminary evidence that the self-assessment of OFI in a patient's home environment is feasible and provides additional information to the physician. The combination of subjective PROM-based and objective app-based OFI assessment support the clinician to evaluate whether or not a patient has responded positively to a healthcare intervention.

We observed that the 6WT served as a good indicator for change in a patient's functional status after ESI, also reflected by the PROMs. The first 2 cases reported marked and clinically meaningful improvements in PROMs, including ODI, COMI, and NRS leg pain. This was in line with a substantial increase in their 6WD after ESI, approaching or exceeding the age-specific normal population reference values. Interestingly, both patients showed a progressive improvement in walking capacity with increasing 6WD already after 3 and 7 days, which continued to improve until the 28-day follow-up. As the anti-inflammatory effect of the steroids effectively lowered a patient's pain and disability level, the 6WD increased. The longitudinal improvement in 6WD, therefore, indicates a good responsiveness of the 6WT to detect change in OFI.

In contrast, the patient in the case vignette III did not benefit from the ESI, according to the lack of improvement in his 6WD. The patient experienced a moderate pain relief just above the MCID; however, this did not translate into a detectable improvement in OFI reflected by the 6WD. Furthermore, the subjective functional status worsened after ESI according to ODI while the COMI showed minor, yet not clinically significant improvements. With the conflicting results of the battery of PROMs, the objective evaluation of walking capacity using the 6WT app provided meaningful and quantifiable additional information with impact on the patient's daily activities to complement the subjective evaluation.

The smartphone-based approach was feasible in our clinical practice and was associated with a low responder burden. Originally designed for the use in cardio-pulmonary diseases, the simple and reliable nature of the 6WT has made it an attractive tool for monitoring patients with a broad range of medical conditions.[13-15] While the 6WT has not yet been systematically validated in spine patients, one major benefit of the spine-specific 6WT app is that specialized equipment other than a smartphone is not required. All 3 patients felt that the app was easy to use and that the 6WT was even better suited to detect changes in their functional status and symptoms when compared to the PROM questionnaires. Smartphone-based measures can be collected longitudinally and repetitively, allowing patients to detect and objectify change in their functional status over time. The good acceptance by patients and the high reliability of app-based 6WT measurements may be an interesting asset to future clinical studies or trials.[16] This small series, together with previously published reports on smartphone-based assessment tools in other neurological diseases,[16,17] suggests that digital outcome measures represent a promising avenue to enable a comprehensive assessment of functional outcome in both research and clinical practice. While the distance walked within a certain time frame is an important measure of function, spine patients also regularly show impaired gait pattern. Therefore, comparing 6WT measurements with more detailed gait analysis by means of shoe insert sensors might be of additional interest in future studies. One disadvantage of smartphone applications as objective outcome measurement for spinal pathologies might be the exclusion of a percentage of the elderly population without smart-

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phones. While this share might further shrink with the ongoing digital transformation, a lack of knowledge in using smartphone apps within the elderly might currently serve as an additional barrier for their successful use.[17] Both of these drawbacks are likely to vanish over time, as the digitalization of the society continues.

The main limitation of this case series is its small sample size, which prevents meaningful statistical analysis. Further investigations to assess the validity and sensitivity of the 6WT, as well as the 6WT's ability to detect changes in functional capacity of patients undergoing spine surgery or ESI, are warranted in adequately powered studies. The definition of the 6WT's "clinically meaningful change of function" (=MCID) will be crucial for its implementation as a standardized and validated outcome instrument. In cardiovascular conditions, a mean change between 43–54 m has been reported as clinically significant previously, but disease-specific MCIDs for the spine must still be determined.[19,20] In addition, future research should focus on cross-validating 6WD results with PROMs, such as NRS leg pain, COMI, and ODI.

CONCLUSION

This patient series suggests that the 6WT is a useful tool to assess outcome and monitor a patient's functional walking capacity before and after lumbar ESI. Our report further demonstrates that self-measurements of the 6WT are feasible in clinical practice and are well-accepted by patients.

CONFLICT OF INTEREST

The authors have nothing to disclose.

SUPPLEMENTARY MATERIALS

Link to the free 6WT smartphone application: 1. Android Google Play Store: https://play.google.com/store/apps/details?id=ch.webgearing.walkingapp&hl=de. 2. Apple App Store: https://apps.apple.com/de/app/6wt-app/id1454002232.

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