Screening for distress, the sixth vital sign, in lung cancer patients:  
effects on pain, fatigue, and common problems—secondary outcomes of a randomized controlled trial

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Abstract

Background: This randomized controlled trial examined the impact of an online routine screening for distress program on physical symptoms and common psychosocial and practical problems in lung cancer outpatients.

Method: Patients were randomly assigned to either the minimal screening group (the Distress Thermometer plus usual care); full screening group (Distress Thermometer, Canadian Problem Checklist (CPC), Pain Thermometer, Fatigue Thermometer, and the Psychological Screen for Cancer Part C, with a personalized report summarizing concerns); or triage (full screening plus option of personalized phone triage). Outcomes included pain, fatigue and psychosocial, practical and physical problems. Patients were reassessed 3 months later.

Results: A total of 549 lung patients completed baseline measures (89% of eligible patients) and 65.9% were retained at 3 months. At 3 months follow-up, significantly fewer patients in the triage group (32.1%) reported pain compared with the minimal screening group (49.6%), but the triage and full screening groups were not significantly different from one another. Patients in the triage group reported fewer problems with coping compared with the minimal and full screening groups and fewer problems with family conflict compared with the minimal screening group. Full screening patients reported fewer problems with breathlessness compared with the minimal screening group. No differences were found among groups in fatigue. Referrals were not associated with changes in outcomes over time.

Conclusions: Routine screening for distress followed by personalized triage resulted in the most benefit for lung patients, with fewer fully screened and triaged patients reporting physical symptoms and psychosocial problems than those only minimally screened.

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Introduction

Lung cancer is often diagnosed late in the disease trajectory, and subsequently patients may have fewer treatment options than is the case with other cancers [1]. As a consequence, disease progression is often rapid, with worsening of existing symptoms and the emergence of new symptoms [1]. In a Canadian population-based study of cancer outpatients, lung patients reported greater symptom burden compared with other cancer patients across the disease trajectory [2], as did lung patients within 12 months of diagnosis [3]. Distress was also more prevalent in new and follow-up lung patients compared to patients with other diagnoses [4,5].

In the last decade, distress has been positioned as the sixth vital sign in cancer care [6], a designation that carries with it the obligation of regular and repeated screening and treatment. Distress is a multifactorial emotional experience that can encompass a range of psychosocial, practical, and physical concerns [7]. The Canadian Partnership Against Cancer (CPAC) advocates for these psychosocial, practical, and physical domains to be included as core components of screening for distress in cancer patients [8]. To assess these concerns in a standardized way, both CPAC and the National Comprehensive Cancer Network recommend that a Problem Checklist should be incorporated into the measure used to screen patients [7,9]. Although the list of problems included in the Problem Checklist may vary depending on the patient population being assessed [8,10], physical and emotional concerns are the most frequently endorsed and contribute to high distress levels [8,10,11–19]. Practical and family concerns are endorsed to a lesser degree; however, these concerns may also contribute to high distress [12,14,15,18].

In lung patients, family, emotional, information, physical, and cognitive problems; as well as pain, fatigue, depression, and anxiety have all contributed to high distress levels [17]. Without intervention, distress remains high in lung patients for at least 6 months post-diagnosis [20]. In lung patients undergoing treatment, fatigue and pain were the two most prevalent and distressing symptoms during the first 6 months following diagnosis; and pain-related distress increased between 3 and 6 months [21]. The presence of these symptoms and the burden they incur suggests that lung patients are an important target population for ongoing assessment and intervention.

Routinely screening for common psychosocial, practical, and physical concerns can better equip healthcare
providers to accurately identify the nature of the distress cancer patients are experiencing, in order to ensure patients access the most appropriate supportive care services [10]. In a group of lung patients within 6 months of diagnosis, 91% reported they would be interested in accessing services to manage symptoms of fatigue, nutrition, depression, anxiety, and pain [22]. However, patients report poor communication with healthcare providers about emotional, practical, and spiritual concerns, as well as prognosis and advance care planning [23]. Moreover, few studies have specifically targeted the lung population when examining the potential benefits of psychosocial interventions [24,25], including screening for distress [17].

In 2010, we reported the results of a randomized controlled trial testing the efficacy of three versions of a screening for distress program on the outcomes of overall distress, anxiety, and depression in both lung and breast cancer patients, but we did not specifically report on common problems, fatigue, or pain. Given that there are a range of physical, psychosocial, and practical concerns that may contribute to patients’ distress levels, the larger study included measures of global distress as well as common problems, including pain, fatigue, psychosocial, and practical items in the screening. These concerns were all included in a triage algorithm that was used to direct patients to services available at our center, should the patient require them. We now report the secondary analyses on the common problems, focusing on lung patients only.

The 2010 study reported the impact of the screening program on distress, anxiety, and depression in newly diagnosed lung and breast cancer patients [26]. Lung patients with the highest levels of initial distress benefited most in terms of reductions in overall distress when they received screening followed by personalized triage to appropriate services [26]. While patients who received referrals to psychosocial services showed greater improvements in anxiety and depression, they did show less improvement in distress than those who did not receive referrals. It was posited that other psychosocial, practical, and physical concerns may not have been resolved at 3 months, thereby contributing to patients’ continued distress [26]. Although we measured and triaged patients on the basis of pain and fatigue as well as distress, anxiety, and depression, these results were not included in the primary outcome paper.

The findings of our previous work also show that uptake of referrals is the most important determinant of outcomes, suggesting that we need to investigate ways to improve uptake of resources, rather than simply focusing on screening alone [26,27]. We therefore investigated receiving a referral to psychosocial services as a marker of receiving appropriate treatment, in order to examine the importance of actually treating identified problems, not just identifying them. Accordingly, the objectives of this study were as follows:

1. To examine the impact of three versions of routine screening at the time of diagnosis on subsequent pain; fatigue; and psychosocial, practical, and physical problems in lung cancer patients 3 months later.
2. To examine the impact of receiving a referral to psychosocial services (as a marker of receiving appropriate treatment for their concerns) on changes in pain; fatigue; and psychosocial, practical, and physical problems reported by patients 3 months later.

Methods

Participants

All ambulatory oncology lung patients 18 years and over attending a large tertiary cancer center in Calgary, Canada, who were either newly diagnosed, new to the lung clinic, or the oncologist they were seeing that day were invited to participate. There were no restrictions based on type of lung cancer or stage of disease. If the person was unable to read or speak English, or was physically unable to complete the screening, the person was counted as ‘excused’, and the reason for nonparticipation was recorded.

Procedures

A detailed description of study trial methodology has previously been reported [26]. Briefly, all eligible patients were approached in the outpatient clinic waiting room by a screening assistant prior to their oncology appointment. The screening assistant introduced the online program. Patients entered their personal health number into the online screening program using handheld tablet personal computers, which provided a touch screen activated by a stylus pen, and were then asked to provide study consent electronically. If the patient consented to the study, a record was opened, which triggered electronic random assignment to one of three conditions in an allocation ratio of 1:1:1. Patients were allocated to either: (i) minimal screening group; (ii) full screening group; or (iii) triage group. Consent ing patients completed the online screening program on the touch screen computer at baseline in the clinic. In addition to usual care, the minimal screening group completed the Distress Thermometer (DT). The full screening group also completed the DT; however, they also completed the Pain Thermometer (PT), the Fatigue Thermometer (FT), the Canadian Problem Checklist (CPC) and the Psychological Screen for Cancer Part C (PSSCAN). Once screened, they received a personalized printout of their report that summarized their concerns and listed the contact details of services that were available to help them with each of the identified concerns. Finally, the triage group completed the same measures as the full screening group and also received a personalized report of their identified concerns. In addition, these patients were also offered the opportunity to speak to a member of the psychosocial team about identified concerns, and the screening team could refer them directly to services the patient wished to use. If the patient received a referral, it was sent to the appropriate service provider(s) and the patient was contacted by the provider for follow-up.

Using the touch screen computer, patients in the full screening and triage groups completed all outcome measures at baseline; the minimal screening group completed the DT only at baseline. All patients were contacted 3 months later by telephone or e-mail to complete outcome measures. The minimal screening group completed the same outcome measures as the full screening and triage groups at 3 months (DT, PT, FT, CPC, and PSSCAN).
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Screening was conducted between May 2006 and October 2007. Procedures were approved by the Conjoint Health Research Ethics Board of the University of Calgary, Faculty of Medicine/Tom Baker Cancer Centre.

Outcome measures

1. FT: Patients were initially asked to indicate whether fatigue was a problem for them (y/n). Patients were also asked to ‘rate your average fatigue during the past week, with 10 being extreme fatigue and 0 being no fatigue’. A cut-off of ≥4 was used to identify cases of clinically elevated fatigue [28]. The use of single-item screening instruments such as the FT and PT is valid for detecting outcomes compared with multidimensional tools [28,29].

2. PT: Patients were initially asked whether pain was a problem for them (y/n). Patients were also asked to ‘rate your worst pain during the past week, with 10 being worst pain and 0 being no pain’. A cutoff of ≥4 was used to identify cases of clinically elevated pain [28].

3. The CPC. Participants indicate the presence or absence of 7 practical (accommodation, transportation, parking, drug coverage, work/school, income/finances, and groceries), 3 physical (sleep, nausea, breathlessness), and 12 psychosocial (burden to others, worry about family/friends, talking with family, talking with medical team, family conflict, appearance; alcohol/drugs, smoking, coping, sexuality, spirituality, and treatment decisions) problems. Three total practical (range 0–7), psychosocial (range 0–12), and physical (range 0–3) problem scores were created by summing each endorsed problem in that domain.

4. DT: Patients were asked to rate their distress level in the last week on a 0–10 visual analogue scale. A review of diagnostic validity studies reported a pooled sensitivity of 77.1% and specificity of 66.1% [30].

5. The PSSCAN Part C [31,32]: measures anxiety and depression using 10 items rated on a five-point Likert scale, ranging from ‘not at all’ to ‘very much so’. The measure has been validated in two separate groups of cancer patients. Cronbach’s alpha ranged from 0.79 to 0.89, and test–retest stabilities ranged from 0.49 to 0.87 [31,32].

Triage algorithm (Figure 1)

Triage was based on a stepped model of psychosocial care ranging from less resource-intensive interventions (classes or one day seminars) to more intensive interventions (counseling) for people with more severe concerns [33,34]. For patients who scored 4 or more on the PT, pain clinic and research nurse phone numbers were provided; for patients who scored 7–10, an extra note was flagged for the medical team. For fatigue, a score of 4–6 prompted a referral to the fatigue class; whereas a score of 7–10 prompted a referral to the fatigue nurse. For patients who endorsed any of the practical problems on the CPC, a referral to resource class or resource social worker was discussed. For patients who endorsed any of the psychosocial items on the CPC, referrals to the coping class or psychosocial resources for counseling or group programs were discussed. If the patient agreed to the referral, referrals were sent to the appropriate service provider(s) and the patient was contacted by the provider for follow-up.

Statistical analysis

The continuous pain score and total psychosocial and physical problems variables were transformed using logarithmic transformation because they were initially non-normally distributed. Follow-up scores for each continuous outcome were compared using a one-way analysis of variance; baseline values could not be controlled for as the minimal screening group did not complete these measures. Independent samples t-tests did confirm that the full screening and triage groups did not differ from one another at baseline.

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**Figure 1. Screening for distress triage algorithms**
The Kruskal–Wallis test assessed total practical problems, as transforming this variable did not improve normality. A percentage of patients in each group reporting the presence of pain and fatigue (yes/no), clinically elevated pain and fatigue scores (i.e., score ≥ 4), and individual problems on the CPC at the 3-month follow-up were compared using chi-square (χ²) tests. All three groups were compared initially using chi-squares. Where significant differences were found, pairwise chi-squares were then run again to compare each group with every other group. A Bonferroni correction was made to the alpha level for the three follow-up tests comparing each of the three groups to all other groups, when a significant overall chi-square result was found. The new alpha level was α = 0.029.

Change scores were calculated for continuous outcomes by subtracting baseline scores from 3-month scores. Negative numbers indicated a decrease in symptoms. Patients in the minimal group were excluded as they did not complete baseline measures. Independent t-tests compared change scores between the full screening and triage groups. The full screening and triage groups were then collapsed, and independent t-tests compared changes scores between referred and non-referred patients. With 117, 108, and 137 participants available across three groups for analysis of the secondary outcomes, the PT and FT continuous scores, there was 99% power to detect medium effect size of f = 0.25 (p < 0.05).

Results

Participants

A total of 549 lung patients (89% of eligible population) provided baseline data, and 362 (69.5%) were retained at 3 months (Figure 2). There were no differences between the three groups at baseline (Table 1).

Baseline symptom prevalence

The presence of pain (y/n) was reported by 51% of full screening and 45% of triage patients. The presence of fatigue (y/n) was reported by 74% of full screening and 65% of triage patients. There were no significant differences between the groups in the prevalence of pain (χ² = 1.54, p > 0.05) and fatigue at baseline (χ² = 3.78, p > 0.05). Overall, the top 10 problems endorsed at baseline included sleep difficulties (52.5%), worry about friends/family (47.2%), breathlessness (40.5%), coping (26.5%), burden to others (26.3%), treatment decisions (25.7%), getting to and from appointments (25.5%), financial (19%), changes in appearance (18%), and nausea (15.8%).

Objective 1

The percentage of patients reporting pain at 3 months was significantly different among the groups (χ² = 8.00, p = 0.02) (Figure 2). Fewer patients in the triage group (32.1%) reported pain compared with patients in the minimal screening group (49.6%) (χ² = 8.00, p = 0.005); however, there was no difference between the full screening (40.7%) and triage groups (χ² = 1.95, p = 0.16). Fewer triage patients (21.9%) reported clinically elevated pain scores compared with the minimal screening group (33.3%) (χ² = 4.17, p = 0.04) (Figure 3). No significant differences were found between the groups on mean PT scores (minimal screening = 2.61 vs. full screening = 2.11 vs. triage = 1.82; F = 1.96, p = 0.142).

Figure 2. Study flowchart
There were no significant differences between any of the groups in the percentage of patients experiencing fatigue ($\chi^2 = 0.46, p = 0.79$), clinically elevated levels of fatigue ($\chi^2 = 0.91, p = 0.63$) (Figure 2), or mean FT scores (minimal screening = 3.74 vs. full screening = 3.32 vs. triage = 3.86; $F = 0.84, p = 0.434$). Across the three groups, the most frequently reported problems at 3 months were breathlessness (41.7%), worry
about friends/family (34.5%), sleep difficulties (30.4%), being a burden (24.1%), changes in appearance (21.1%), and coping (21.1%). There were no significant differences between the groups on mean total physical (minimal screening = 1.61 vs. full screening = 1.53 vs. triage = 1.24; $F = 1.25, p = 0.29$), psychosocial (minimal screening = 1.03 vs. full screening = 0.82 vs. triage = 0.85; $F = 1.65, p = 0.19$), or practical problems (minimal screening = 0.47 vs. full screening = 0.45 vs. triage = 0.46; $H = 2.98, p = 0.23$) at 3 months.

Overall, the percentage of patients reporting problems with coping at 3 months was significantly different among the groups ($\chi^2 = 9.04, p = 0.011$). Fewer patients in the triage group reported a problem with coping (12.9%) compared with patients in the minimal (23.9%) and full (26.9%) screening groups ($\chi^2 = 5.75, p = 0.017$) (Figure 4). The percentage of patients reporting problems with family conflict at 3 months was significantly different among the three groups ($\chi^2 = 7.59, p = 0.022$). Fewer triage patients reported problems with family conflict compared with the minimal screening group ($\chi^2 = 3.57, p = 0.05$). Fewer full screening patients reported problems with family conflict compared with the minimal screening group ($\chi^2 = 5.88, p = 0.015$). Fewer patients in the full screening group reported breathlessness than the minimal screening group ($\chi^2 = 4.68, p = 0.03$). There was a trend for fewer triage patients to report problems with breathlessness than the minimal screening group ($\chi^2 = 3.53, p = 0.06$).

**Objective 2**

On average, patients reported an increase in pain and fatigue and a decrease in the number of reported psychosocial and practical problems. Total physical problems indicated little change (Table 2). There were no significant differences in change scores between the full screening and triage groups.

Of the 549 participants, 69 (12.6%) were referred to services. Significantly more patients in the triage group were referred ($n = 39, 19.6\%$) compared with the minimal ($n = 14, 8.0\%$) and full screening ($n = 16, 9.2\%$) groups ($\chi^2 = 14.16, p = 0.001$). Services most frequently referred to included individual counseling ($n = 46$), nutritionist ($n = 27$), resource class ($n = 26$), resource social worker ($n = 14$), and external social workers ($n = 11$). The main reason for not using services reported by patients was that they ‘did not need help’ ($n = 216$).

Receiving a referral was not significantly associated with changes in pain; fatigue; and practical, psychosocial, and physical problems over time (Table 2). A subgroup analysis explored the impact of referrals on change scores within the triage group only finding no significant differences between referred and non-referred patients.

**Discussion**

Our first objective was to examine the impact of screening for distress at the time of diagnosis on subsequent symptoms in lung cancer patients 3 months later. Patients who

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**Figure 3.** Percentage of patients in each group reporting the presence of pain and fatigue, and scores of 4 or more on the Pain Thermometer and Fatigue Thermometer at 3 months. *Triage significantly lower than minimal screening groups; $p < 0.05$.

**Figure 4.** Percentage of patients in the minimal, full screening, and triage groups endorsing Canadian Problem Checklist items at 3-month follow-up. *$p < 0.05$.
received screening followed by triage were less likely to report any pain at 3 months compared with the minimal screening group. Fewer patients in the triage group also reported clinically elevated pain scores (≥4) compared with the minimal screening group. These reductions in pain are important, because pain is a highly distressing symptom that can interfere with sleep [35], daily activities [36], and quality of life [37,38]. Pain is also associated with suicidal ideation [39] and psychological distress in patients newly diagnosed with unresectable non-small cell lung cancer [40] and inoperable lung cancers [41]. Lung patients experience worsening of pain in the 6 month following diagnosis [40], as do survivors 5-year post-diagnosis [38]. Given the long-lasting burden of unresolved pain, the fact that fewer patients in the triage group reported pain at 3 months is therefore important. In terms of overall referrals, 25, 29, and 64 patients were referred to any supportive care service in the minimal screening, full screening, and triage groups, respectively. Hence, more people in triage were referred to any of a number of supportive care services. Given that psychosocial care has been shown to reduce stress and depression, which have been implicated in pain control, this may be one explanation for the beneficial effects seen. This method of screening offers a viable strategy for ensuring that pain is identified and managed in a timely way.

In contrast to the pain outcomes, there were no benefits of screening with triage on patients’ fatigue levels over 3 months. This may reflect the nature of lung cancer, which is often diagnosed later in the trajectory resulting in lower survival rates, fewer treatment options, and increased symptom burden as the disease progresses [3,42,43]. In this sample, 65% of participants were diagnosed in later stages of disease and 55% had received surgery, chemotherapy or radiation therapy alone, or in combination in the meantime. Each of these interventions is associated with increased fatigue, and lung patients are more likely to report fatigue of 6-month duration compared with other cancer patients [44]. Fatigue has a range of potential disease and treatment-related causes [45], and 3 months may have been insufficient time to address the level of burden of these patients.

Examine common problems can help healthcare providers to identify those concerns contributing to distress in order to offer appropriate practical and psychological assistance. Compared with minimal screening patients, fewer triage patients reported problems with coping and family conflict; and fewer full screening and triage patients reported problems with breathlessness. The specificity of these improvements is interesting and may be related to the specific referrals patients received to help with these issues. However, the number of referrals received from these services was small, and further work is needed to examine the benefits of specific referrals on these problems. Breathlessness is typically one of the most burdensome symptoms in lung patients [1] and has been found to worsen over time [37] but can be treated if identified [46]. Coping and emotional distress may predict survival [47,48] and quality of life in lung patients [37], and are explicitly targeted in psychosocial interventions. Although the number of patients reporting problems with family conflict was small, it is a serious problem and patients may be less likely to initiate discussions unless it is specifically screened.

In summary, the benefits of screening followed by triage were most evident for pain, coping, family conflict, and breathlessness. Compared with patients who received minimal screening, fewer patients receiving triage reported pain at 3 months, and fewer patients reported clinically elevated levels of pain. Fewer patients in the triage group also reported problems with coping and family conflict, whereas fewer patients who received full screening reported problems with breathlessness.

A greater percentage of people in the triage group did report accessing services than in the full and minimal screening groups, which was expected and one explicit intention of the program. However, unlike for the primary outcomes of anxiety and depression [26], receiving a referral was not associated with changes in pain, fatigue, or problems. Even when the impact of referrals was examined in the triage group alone, no significant differences were found between the referred and non-referred patients. Because the overall number of referrals was quite low, these analyses may have lacked sufficient power to detect a significant difference. Although referrals did occur

Table 2. Change in mean pain, fatigue, and common problem scores between baseline and the 3-month follow-up in full screen and triage groups, and referred and non-referred participants

<table>
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<tr>
<th></th>
<th>Full screen (n = 108)</th>
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<th>p value</th>
<th>Referred (n = 27)</th>
<th>Not referred (n = 218)</th>
<th>p value</th>
<th>All patients (n = 245)</th>
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<td>Mean</td>
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SD, standard deviation.
between baseline and follow-up, a longer follow-up time may have provided a clearer picture of the benefits of referrals on subsequent levels of outcomes. It is important to note that overall referral levels were quite low, even in the triage group, testament to the generally low rate of usage of supportive care services by lung cancer patients [49]. The small number of referrals made in this sample prevents us from making any concrete assertions regarding the benefits of referrals on pain, fatigue, and common problems. The most commonly reported reason given by patients for not taking up services was that they did not feel they needed help. Perhaps the conversation following screening better equipped providers to identify issues they could manage within their own setting rather than automatically referring patients on. Additionally, patients were screened and triaged at the time of diagnosis only. It is recommended that patients be screened repeatedly to ensure that concerns are identified and managed in a timely manner [9]. Providing more opportunities for connecting patients to services may have also resulted in more appropriate referrals and greater benefits for patients.

Although this study has distinct strengths, including the large sample size and the focus on a single diagnostic group, there are some limitations. We were only able to retain approximately 64.7% of patients with lung cancer at 3 months, due primarily to disease progression and mortality; however, this attrition rate is consistent with other studies in this population. Multiple comparisons were made between the groups; however, we attempted to address the potential inflation of alpha using Bonferroni corrections. The change scores for the two screening groups indicate an overall increase in pain and fatigue and fewer problems over time; however, because they were lacking baseline measures of pain and fatigue, we do not know whether the minimal group experienced similar changes. It may be that the 3-month follow-up period was insufficient to reduce pain and fatigue or that both full screening and full screening plus triage were equally effective in minimizing the anticipated increase in the physical symptoms that often occurs in this population. However, the randomization procedure showed no differences between the groups in demographic, disease, and medical variables at baseline so it is fair to assume the third randomized group, minimal screening, would also be matched at baseline.

The CPC includes only one item to assess the presence or absence of each particular concern. Like the DT, PT, and FT, the CPC measure is meant to be used as a first-line screening measure that can direct the healthcare provider’s attention to the identified area of concern. This should be followed by further, more comprehensive assessment of the concern to determine the severity or complexity and the appropriate intervention required (if any). Further work is needed to confirm the benefits of screening with triage using comprehensive follow-up assessments.

In summary, lung patients receiving screening followed by personalized triage at the time of diagnosis reported less pain and fewer problems with coping, breathlessness, and family conflict 3 months later compared with patients who received minimal screening only. Given recent recommendations that screening be undertaken routinely in cancer patients, further work is needed to examine the potential long-term benefits of repeated screening with triage. Further, there is a need to examine best practice approaches for implementing sustainable and effective screening for distress programs within existing clinical settings and ways to improve levels of accessing services in these patients.

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Conflict of interest

There are no known conflicts of interest for the authors.

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