である[17]。また，情報化技術の難解さ．安くない情報化コストを考えると，医師会のように緩やかな結合で成り立っている団体で強制はできない。情報化においても個々の医療機関の自主性は尊重されるべきである。当面は「医療者向け情報，一般向け情報の発信に努めること」，「病診連携の中核（連携支援ツール）を提供すること」，「個々の医療機関IT化を支援すること」が重要であり．安全で容易なネットワークを用意し．情報化の利点を実感できるサービスを提供し続けることが重要である。慌てなくても遠くない将来，医療の情報化は必ず達成される。全国の各地域医師会で情報化へのひたむきな努力を続けている同志には励ましを送りたい。

まとめ

医療法改正の動き，がん対策基本法の制定から今後の医療連携のあり方を概括した。医療連携の核として「患者と医療提供者を調整する組織の役割」(相談支援機能を有する部門（相談支援センターなど）) のもつ意義と，医療機能情報の共有化の必要性．実現への方策を論じた。医療連携部門の拡充こそが地域医療，病院機能の効率化と活性化の要である。

本論文は第3次対がん10か年総合戦略研究事業"患者の視点を重視したネットワークによる在宅がん患者支援システムの開発"研究（H 16—3次がん—一般035）の成果による。

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● 特 集 ● チーム医療で進める癌治療

癌治療とクリニカルパス

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〔*Jpn J Cancer Chemother* 33(11): 1568-1570, *November*, 2006〕

Clinical Pathways in the Treatment of Cancers: Toshiaki Tanaka[*1], Taeko Tousaka[*2] and Hiromasa Fujita[*1] (*[1]*Dept. of Surgery, Kurume University School of Medicine,* *[2]*Nursing Dept., Kurume University Hospital*)

Summary

At the beginning, a clinical pathway was first introduced for the purpose of standardizing the treatment, providing high quality management and shortening hospital stays in the managed care health system in USA. This has been rapidly accepted also in Japan.

The clinical pathway has also been gradually introduced in the treatment of malignant diseases, including chemo/radiotherapy and surgery. In Kurume University Hospital, clinical pathways are now applied for 50% of in-patients, and those for cancer patients have a large role in routine clinical practice. The progress of our pathways for cancer patients is here reported. Key words: Clinical pathway, Cancer, Chemotherapy, Chemo/radiotherapy, surgery, Corresponding author: Toshiaki Tanaka, Department of Surgery, Kurume University School of Medicine, 67 Asahi-machi, Kurume 830-0011, Japan

要旨 クリニカルパスは治療の標準化，治療の質の向上さらに入院日数の短縮を目的に米国のマネージドケアのなかから生まれた。現在，わが国でも急速に普及している。癌治療においてもクリニカルパスを用いる施設は徐々に増加し，化学/放射線療法や手術などその領域は多岐にわたっている。当院ではクリニカルパス利用率は50%に達しており，癌治療におけるクリニカルパスの使用も年々増加してきている。これまでの当院での癌治療におけるクリニカルパスの取り組みを紹介する。

はじめに

クリニカルパスは，米国においてDRG/PPS導入によるマネージドケア（managed care）のなかから在院日数短縮，医療費削減を図る必要性から1980年代半ばに生まれた。両国の医療制度の根本的な相違からか，わが国においてクリニカルパスの認知度はあまり向上しなかった。わが国においては，まず医療の質の向上や患者サービスの面からクリニカルパスを導入した施設が徐々に増加した。1999年に日本クリニカルパス学会が設立され，その後急速に普及してきた。

2003年には特定機能病院にDPCが導入された。DPCを導入する医療機関拡大とともに，医療の効率化の観点からも，クリニカルパスの普及はさらに進むと考えられる。

クリニカルパスは医療を円滑，かつ効率的に遂行するための治療計画書であり，同時にマネージメントツールでもある。医師，看護師，薬剤師など多職種からなる医療者が情報を共有することにより，チーム医療の実践を容易ならしめる。

クリニカルパスの利点として，医療の標準化があげられる。同一の治療でも，従来は医師によってばらつきがみられたが，クリニカルパスを用いることにより治療法が統一される。結果のばらつきだけでなく，時系列的なばらつきも是正できる。さらに治療の内容・スケジュールが明確に示されることから，処方ミスや検査などの「抜け」がなくなり，医療の質の向上につながるだけでなく，患者への治療情報の提供の面でも効果が大きい。結果的にクリニカルパスはリスクマネージメントやインフォームド・コンセントのツールとしての意味もある。

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0385-0684/06/¥500/論文/JCLS

＜特集＞第17回日本在宅医療研究会学術集会

医療者が考える末期がん患者の退院阻害要因

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Discharge Interference Factors of Terminally Ill Cancer Patients: A Questionnaire Survey Provided by Medical Staff at the Cancer Center Hospital: Kaori Tadokoro, Hiromi Uruki, Junko Kamiya and Masahito Tanimizu (*National Hospital Organization Shikoku Cancer Center*)

Summary

Despite of a terminally ill cancer patients' state of illness being stable, there will be a case where a patient loses his or her chance to be discharged due to an increase in length of hospitalization. We studied a questionnaire survey that was provided by medical staff at the cancer center hospital, and discussed how to support or encourage patients to cooperate with medical staff in order to attain shorter hospitalization. Key words: Discharge interference factor, Discharge support, Cooperation with other medical constitutes

要旨　末期がん患者のなかには病状が安定していても，入院が長引き在宅で過ごすチャンスを逃す場合がある。医療者が同じ意識をもって退院支援に取り組むため，医師，看護師が考える退院阻害要因を調査したので報告する。

はじめに

残された時間をどう過ごしたいのか，どう介入すればよいのか，われわれ医療者は常に試行錯誤している。医療者間が同じ意識をもって退院支援に取り組むため，今回，医師，看護師が考える退院阻害要因を調査し，今後取り組む対策を考察した。

I. 研究方法

1. アンケートによる実態調査研究

1) 対象: 当院の医師70名，看護師252名。

2) 期間: 2005年5月～1年間。

3) 調査票（図1): 質問1. 予備調査で得られた患者側，医療者側，システム要因の三つのカテゴリーで13の質問項目を作成し，さらに細かい内訳について考えられる因子を自由記述で求めた。質問2. 13項目のなかから特に重要だと思われる要因三つを選んでもらった。

4) 分析: KJ法，単純集計。

II. アンケート調査結果

1) 調査回収率: 医師30%（21名），看護師86.9%（219名），全体71.4%（230名）。

2) 属性: 医師; 平均年齢39.0歳，臨床経験年数15.1年，当院での勤続年数4.5年。看護師; 平均年齢35.5歳，臨床経験年数12.9年，当院での継続年数9.4年。

3) 予備調査から，患者側，医療者側，システム要因の三つのカテゴリーで13項目の退院阻害要因に類型化された（図2）。

4) 本調査結果: 質問1. 退院阻害要因の内訳をグルーピングし表1に示した。

また，グルーピングしきれなかった医師のその他の意見として，「医療者の姿勢・考え方は関係ない」，「退院支援への興味不足」などがあった。看護師のその他の意見として，「介護者の仕事の問題」，「医療者も退院できないと思い込んでいる」，「情報をスタッフが共有していない」などがあった。

質問1，2より→1. 医師・看護師間で相違があった退院阻害要因は，記述結果より，医療提供者の姿勢・考え方だった。2. 医療者が主要として考えていた退院阻害要因は，①介護問題，②患者の不安，③当院・治療への依存・固執で患者側の要因であった（図3）。

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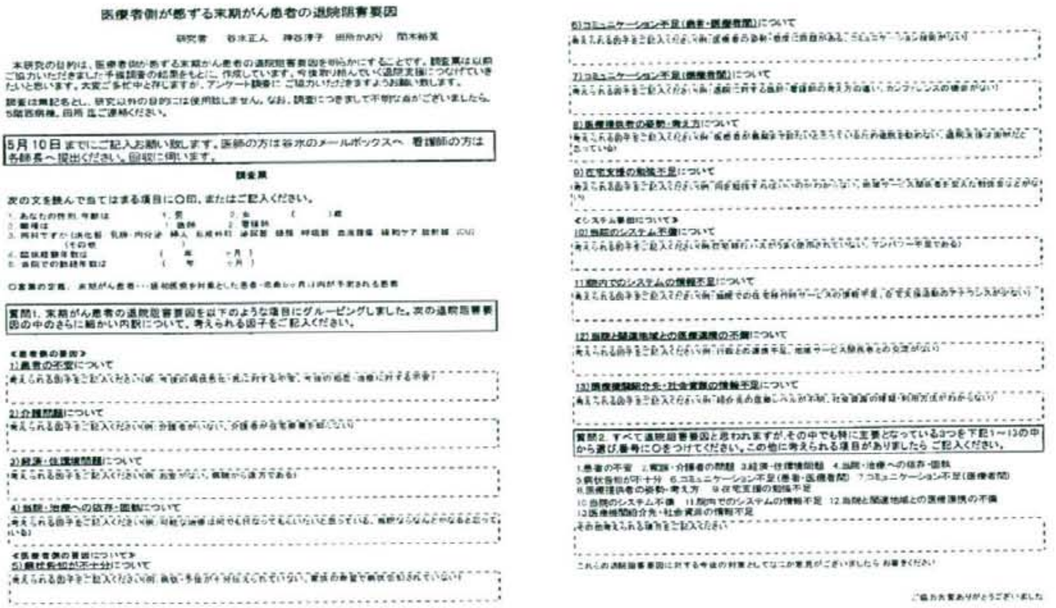
医療者側が感ずる末期がん患者の退院阻害要因

5月10日までにご記入お願い致します。医師の方は谷水のメールボックスへ　看護師の方は各師長へ提出ください。回収に伺います。

調査票

次の文を読んで当てはまる項目に○印，またはご記入ください。

質問1. 末期がん患者の退院阻害要因を以下のような項目にグルーピングしました。次の退院阻害要因の中のさらに細かい内訳について，考えられる因子をご記入ください。

《患者側の要因》
1)患者の不安について
2)介護問題について
3)経済・住環境問題について
4)当院・治療への依存・固執について
《医療者側の要因について》
5)病状告知が不十分について
6)コミュニケーション不足(患者・医療者間)について
7)コミュニケーション不足(医療者間)について
8)医療提供者の姿勢・考え方について
9)在宅支援の勉強不足について
《システム要因について》
10)当院のシステム不備について
11)院内でのシステムの情報不足について
12)当院と関連地域との医療連携の不備について
13)医療機関紹介先・社会資源の情報不足について

質問2. すべて退院阻害要因と思われますが，その中でも特に主要となっている3つを下記1～13の中から選び，番号に○をつけてください。この他に考えられる項目がありましたら ご記入ください。

1.患者の不安　2.家族・介護者の問題　3.経済・住環境問題　4.当院・治療への依存・固執
5.病状告知が不十分　6.コミュニケーション不足(患者・医療者間)　7.コミュニケーション不足(医療者間)
8.医療提供者の姿勢・考え方　9.在宅支援の勉強不足
10.当院のシステム不備　11.院内でのシステムの情報不足　12.当院と関連地域との医療連携の不備
13.医療機関紹介先・社会資源の情報不足

ご協力ありがとうございました

図 1　調 査 票

図 2　予備調査より得られた退院阻害要因の抽出と類型化

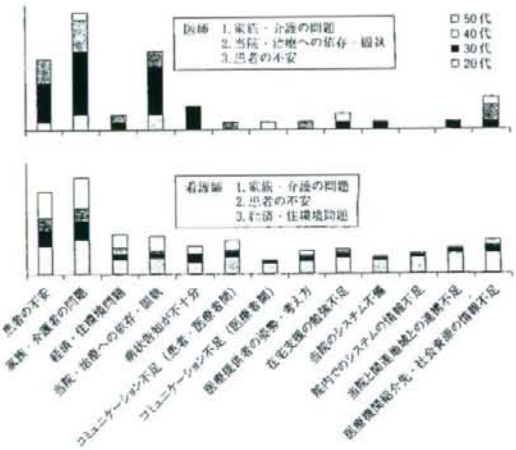

図 3　主要だと思われる退院阻害要因の選択

III. 考　察

患者側要因に対する対策として当たり前のことだが，患者の立場に立って考えることである。不安いっぱいで入院した患者・家族に対し，早い段階から積極的にかかわり，不安に耳を傾けなければならない。病院でも家庭での生活をイメージして介護・医療に参加していただき，入院中から地域スタッフも介入して継続したケア・医療・安心を提供したいと考える。

医療者側要因に対する対策として，まず医師による治療のゴール・入院目的の明確化が必須であり，退院の話を医師がいかに早く行うかであろう。当院での治療の限界，退院後のフォローまで IC でできることが理想である。定期的な退院カンファレンスによる意識の統一，退院阻害要因，退院機会の見極めも重要である。

システムの要因に対する対策として，退院支援システムの構築が第一にあげられる。当院では 2006 年 4 月新病院設立とともにがん相談支援・情報センターが開設した。院内外連携の強化・円滑化をめざしている (表 2)。退院阻害要因は，医療者側の要因，システムの要因も加わり，複雑に相互に関連して存在する。がん相談支援・情報センターを中心に，入院早期に地域での看護・看取りなどを視野に入れた計画を立て，医療チームが同じ意識をもって退院支援ができるシステム作りに取り組んでいきたい。

表 1 退院阻害要因の内訳

<患者側要因>	医師の意見	共通意見	看護師の意見
1. 患者の不安	・処置・治療に対する不安	・今後の病状悪化 ・死の恐怖	・急変時の対応
2. 介護問題	・家族への遠慮	・介護者が不在 ・在宅療養についての知識不足 ・家族の負担	・介護者が高齢
3. 経済・住環境問題	・病院から遠方	・お金がない ・通院困難 ・住宅の問題	・地域に十分な施設がない
4. 当院治療への依存・固執	・当院スタッフに依存している	・当院なら何とかなると思っている ・当院への期待・希望 ・当院にいる安心感	・見捨てられたという思い
<医療者側要因>			
5. 病状告知が不十分	・患者の意欲・希望は奪いたくない	・家族の希望で告知できない ・患者・家族が理解できていない	・病状予後が十分伝えられていない
6. コミュニケーション不足（患者・医療者間）	・コミュニケーション不足 ・患者・家族の理解不足	・業務が多忙	・コミュニケーション技術がない ・医療者の姿勢・態度に問題がある
7. コミュニケーション不足（医療者間）	・有意義なカンファレンスができていない	・医師・看護師の考え方の違い ・カンファレンスの機会がない	・話す時間がない
8. 医療提供者の姿勢・考え方	・最後まで治療すべきである ・最後まで診たいと思っている	・退院への準備が面倒で消極的	・退院支援システムが理解できていない ・退院可能な判断が難しい
9. 在宅支援の勉強不足	・在宅支援システムがよくわからない	・勉強会がない ・何を勉強すればよいかわからない	・社会資源についての情報不足
<システムの要因>			
10. システム不備	・緊急対応ができない	・マンパワー不足 ・パスが上手く使用されていない ・在宅移行支援の情報不足	・退院できるタイミングを逃す
11. 院内でのシステムの情報不足	・システムを知らない	・在宅移行時サービス情報不足	・在宅支援活動のアナウンスが少ない ・活動内容が少ない
12. 医療連携不備	・医療連携の窓口を持っている病院が少ない	・行政との連携不足 ・地域サービス関係者との交流会が少ない	・連携方法を知らない
13. 医療機関の紹介先・社会資源の情報不足	・紹介先・医師を見つけるのが大変	・紹介先の医療レベルの情報が少ない ・社会資源の種類・利用方法を知らない	・在宅に興味がない

表 2 抽出された退院阻害要因に対する対策

1. 患者側要因への対策
   - 医師による治療のゴール，入院目的の明確化
   - 早い段階から家族とかかわり，不安に耳を傾ける（MSW のかかわり）
   - 退院後も精神的サポートを行う（緩和ケア外来・がん相談支援・情報センター）
   - 患者・家族に病院での介護，医療に参加していただく
   - 入院中から地域スタッフが介入し継続したケア，医療を保証する
   - 退院と同時にサービスが受けられるよう介護保険の申請
2. 医療者側要因への対策
   - 医師による治療のゴール，入院目的の明確化
   - 家族の不安に耳を傾ける
   - 患者・家族の理解力を考慮した上での病状告知
   - 定期的な退院カンファレンスによる退院阻害要因，退院機会の見極め
   - 患者・家族教育（公開セミナー）
   - 退院調整，在宅支援の勉強会
3. システム要因への対策
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   - 地域の医療福祉関係者を含めた勉強会，カンファレンス，交流会

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Original Article

Artificial Hydration Therapy, Laboratory Findings, and Fluid Balance in Terminally Ill Patients with Abdominal Malignancies

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Abstract

To explore the association between hydration volume and laboratory findings, and between calculated fluid balance and changes in clinical signs of dehydration and fluid retention in terminally ill cancer patients, a secondary analysis of a large multicenter, prospective, observational study was performed. The study enrolled 125 abdominal cancer patients who received laboratory examinations in the last week before death. Patients were classified into two groups: the hydration group (n = *44*), *who received 1 L or more of artificial hydration per day both 1 and 3 weeks before death, and the nonhydration group* (n = *81*). *The mean albumin level 1 week before death was significantly lower in the hydration group than in the nonhydration group, and the interaction between hydration group and decrease in the albumin level was statistically significant after adjusting multiple covariates (from 2.8 ± 0.68 mg/dL 3 weeks before death to 2.4 ± 0.56 mg/dL 24 hours before death in the hydration group vs. a decrease of 2.8 ± 0.53 to 2.6 ± 0.45 mg/dL in the nonhydration group,* P = *0.015). There was no significant difference between the groups in the mean blood urea nitrogen/creatinine, sodium, or potassium levels 1 week before death. Among 53 patients who had oral fluid intake of less than 500 mL/day throughout the last 3 weeks and completed a fluid balance study, the median of calculated fluid balance was −400 mL/day 3 weeks before death, −521 mL/day 1 week before death, and −421 mL/day 24 hours before*

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death. Calculated fluid balances did not significantly differ between the patients with deterioration of dehydration signs, edema, ascites, and pleural effusion during the final 3 weeks and those without. These data suggest that active artificial hydration might result in hypoalbuminemia, with no clear beneficial effects on normalizing blood urea nitrogen/creatinine, sodium, or potassium levels. Fluid balance did not significantly correlate with changes in dehydration—and fluid retention—signs. Calculated fluid balance is not an appropriate alternative to direct monitoring of patient symptoms. More studies are needed to determine the clinical efficacy of artificial hydration for terminally ill cancer patients. J Pain Symptom Manage 2006;31:130–139.

Key Words
Palliative care, dehydration, water depletion, rehydration, neoplasm

Introduction

The dehydration–rehydration problem is one of the most important issues in the recent literature on end-of-life care.[1] Although the primary focus of medical treatment should be placed on patient comfort in the late stages of cancer, an empirical survey revealed that laboratory findings still comprise an important factor when physicians determine the indications for artificial hydration therapy.[2] Therefore, it seems important to clarify the effects of artificial hydration therapy on laboratory data in terminally ill cancer patients. Existing empirical studies have suggested that blood urea nitrogen (BUN) and creatinine levels tend to be higher in patients who do not receive artificial hydration therapy than in patients who receive artificial hydration, but that mean sodium and potassium levels are essentially normal even when artificial hydration therapy is not performed.[3–6] However, these studies were single institution studies, and, to our best knowledge, there are no multicenter prospective studies to explore the association between hydration practice and laboratory findings in terminally ill cancer patients. Moreover, while a fluid balance study is a classical method for monitoring the treatment effects of intravenous hydration therapy,[7–9] no studies have been reported about its usefulness in palliative care settings.

The primary aims of this study were thus to explore the association between (1) hydration volume and laboratory findings and (2) calculated fluid balance and the changes in clinical signs of dehydration and fluid retention during the last 3 weeks of life in terminally ill cancer patients.

Methods

This was a secondary analysis of data collected during a multicenter, prospective, observational study to investigate the associations between hydration volume and patient symptoms in the last 3 weeks of life in terminally ill patients.[10,11] The participants were consecutive, terminally ill cancer patients treated in 14 oncology units, 19 palliative care units, and 4 home-based palliative care programs in Japan. Patients were considered potential participants if they met the following inclusion criteria: (1) older than 20 years; (2) life expectancy estimated by a physician to be 3 months or less; and (3) incurable malignancy of lung or abdominal origin (excluding hepatic malignancies). Exclusion criteria were (1) liver cirrhosis, renal failure, nephritis syndrome, protein-losing enteropathy, intra-abdominal shunt for ascites, hypercalcemia, endocrine disorders, and vital organ complications unrelated to underlying malignancies; (2) surgical, radiological, or oncological treatments in the 3 weeks prior to study inclusion; (3) existing communication difficulty; and (4) the use of artificial enteral nutrition. Patients were enrolled from August 2002 to February 2003, and followed up until March 2003.

To explore the association between hydration volume and the laboratory findings in the final week of life, we analyzed data for patients who received laboratory examinations during the last week. Laboratory examinations were performed for clinical purposes, and we investigated potential sampling bias by comparing the backgrounds of the patients who did and did not

receive laboratory examinations. To explore the associations between calculated fluid balance and the changes in clinical signs of dehydration and fluid retention, we analyzed data from patients who achieved oral fluid intake of 500 mL/day or less through the final 3 weeks and had complete fluid balance data. We chose this population, because we believe strict measurements of oral intake caused unacceptable ethical and practical burden for patients.

The patients received ordinary treatments from their institutions. From the time of study inclusion, the primary responsible physicians prospectively evaluated patients weekly as a part of routine practice, and recorded fluid balance variables, laboratory findings, and clinical signs of dehydration and fluid retention on a structured data-collecting sheet. As covariates, we recorded primary and metastatic tumor sites, performance status, amount of oral intake of fluids, presence or absence of vomiting, intestinal obstruction, requirement for intestinal/ascites/pleural drainage, and use of diuretics.

This study was approved by the Institutional Review Board of each hospital, and conducted in accordance with the Helsinki Declaration.

Measurements

Clinical Signs of Dehydration and Fluid Retention. The rationale for this assessment schedule was described in the original study.[10,11] The degree of dehydration was assessed on the basis of three physical findings: moisture on the mucous membranes of the mouth (0: moist, 1: somewhat dry, 2: dry), axillary moisture (0: moist, 1: dry), and sunkenness of eyes (0: normal, 1: slightly sunken, 2: sunken). These signs were selected due to their significant correlations with biological dehydration, as previously confirmed in elderly patients.[12–14] Ad hoc dehydration score (range 0–5) was calculated as the total of these three scores. A higher score thus indicated a higher level of dehydration.

The severity of peripheral edema was determined through the examination of seven regions: the hands, forearms, upper arms, feet, lower legs, thighs, and trunk. Peripheral edema severity was scored based on the degree of increased skin thickness in the middle of each region (0: none; 1: mild, thickness of <5 mm; 2: moderate, 5–10 mm; 3: severe, >10 mm). The peripheral edema score (range 0–21) was calculated as the total of the severity scores for the seven regions. A higher score indicated more severe edema.

Pleural effusion and ascites were each rated on a scale of 0–2 (0: physically nondetectable, 1: physically detectable but asymptomatic, 2: symptomatic or tense ascites). We did not use diagnostic imaging to determine pleural effusion and ascites severity, due to unacceptable burden for patients.

Fluid Balance. For calculations of fluid balance, we recorded volume of urine, fluid drainage (intestinal, pleural, or ascites), and vomiting as output data. These parameters were measured based on clinical requirements. The daily volume of fluid drainage and vomiting was defined as the mean value of total daily volume in the previous week. Fluid balance was calculated by subtracting the total daily output (the total amount of urine, vomiting, and intestinal, pleural, and ascites drainage) plus insensible water loss (assumed as 500 mL/day) from the total daily volume of artificial hydration.[2–4,9,15] Oral intake fluid was not included, because all patients enrolled in this analysis consumed 500 mL/day or less throughout the last 3 weeks.

Statistical Analyses

Due to its exploratory nature, we performed multiple analyses in this study.

Association Between Hydration Volume and Laboratory Findings. We divided patients into two groups: those who received artificial hydration of 1 L/day or more during both 1 week and 3 weeks before death (hydration group) and those who did not (nonhydration group). This classification was determined on the basis of actual data distributions, and the other classifications achieved similar results.

First, we compared the albumin, BUN/creatinine, sodium, and potassium levels in the last week between the hydration and nonhydration groups. Second, we compared the prevalence of hypoalbuminemia (<2.0 g/L), azotemia (BUN/creatinine >72), hypernatremia (>145 mmol/L), hyponatremia (<130 mmol/L), and hyperkalemia (>6.0 mmol/L) in the last week between the groups. Third, we examined the interactions

between hydration group and the changes in albumin, BUN/creatinine, sodium, and potassium levels during the last 3 weeks with repeated measurement analysis. The last analysis was conducted only on the patients who had laboratory examinations both 3 weeks and 1 week before death. To adjust for the potential effects of covariates, we compared the frequency of each covariate between the hydration and nonhydration groups, and thereafter, we conducted subgroup analyses for patients with covariates whose frequency was significantly different between the groups. In addition, we calculated adjusted *P*-values by entering the covariates into the repeated measurement analysis models.

Associations Between Calculated Fluid Balance and Clinical Signs of Dehydration and Fluid Retention. We compared the calculated fluid balances 1 week before death between the patients whose dehydration and edema scores increased (by three or more points) and ascites and pleural effusion scores increased (by one or more point) in the final 3 weeks and those whose scores did not increase. Then, we calculated correlation coefficients between calculated fluid balance and the changes in these scores during the last 3 weeks.

Univariate analyses were conducted using the Chi-square test (Fisher's exact methods), Student's *t*-test, or Mann-Whitney *U*-test, where appropriate. All analyses were performed using the Statistical Package for Social Science (ver. 11.5).

Results

Of 734 patients initially recruited, 424 patients were excluded due to short administration periods of less than 3 weeks ($n = 323$), longer survival over observation periods ($n = 35$), prior communication difficulty ($n = 33$), medical complications ($n = 27$), discharge ($n = 5$), or use of artificial enteral nutrition ($n = 1$). Thus, a total of 310 patients completed the original study, and 226 patients had abdominal malignancies. For this study, data from a total of 125 patients (55%) who received laboratory examinations during the last week were analyzed. There were no statistically significant differences in patient age, gender, primary site, performance status, or treatment settings between the included and excluded patients (Table 1).

Table 1
Characteristics of Included and Excluded Patients with Abdominal Malignancies

	Included ($n = 125$)	Excluded ($n = 101$)	*P*
Age	67 ± 13	69 ± 10	0.25
	% (*n*)	% (*n*)	
Gender (male)	49 (61)	46 (45)	0.53
Primary site			
Stomach	38 (48)	26 (26)	0.39
Colon	22 (27)	14 (20)	
Pancreas	14 (17)	12 (17)	
Rectum	14 (18)	12 (18)	
Bile duct	4.0 (5)	4.8 (7)	
Ovary	4.0 (5)	3.4 (5)	
Others	7.2 (9)	5.5 (8)	
Performance status at enrollment			
≤2	23 (29)	19 (19)	0.20
3	39 (49)	43 (43)	
4	38 (47)	39 (39)	
Treatment settings			
Oncology	26 (32)	17 (17)	0.11
Palliative care/home	74 (93)	84 (84)	

Association Between Hydration Volume and Laboratory Findings

Table 2 summarizes patient characteristics of the hydration and nonhydration groups. There were significant differences in the frequency of peritoneal metastases, the degree of oral intake of fluids, and the frequency of intestinal drainage between the groups. The mean hydration volume in the hydration group was 1458 ± 514 mL/day 3 weeks before death, 1296 ± 413 mL/day 1 week before death, and 857 ± 622 mL/day 24 hours before death. Hyperalimentation was performed in 59% of the hydration group ($n = 26$) 3 weeks before death and in 27% ($n = 12$) 24 hours before death. All artificial hydration was performed via intravenous routes.

Albumin, BUN/Creatinine, Sodium, and Potassium Levels in the Last Week

In the entire sample, in the subgroups of patients with peritoneal metastases, and in the subgroups of patients with oral intake of fluids <500 mL/day, the mean albumin levels were significantly lower in the hydration group than in the nonhydration group (Table 3).

Table 2
Patient Characteristics of Hydration and Nonhydration Group

	Hydration Group ($n=44$)		Nonhydration Group ($n=81$)		P
Age	66 ± 14		68 ± 12		0.41
	%	n	%	n	
Gender (male)	55	(24)	46	(37)	0.34
Primary site					0.082
Stomach	55	(24)	30	(24)	
Colon	18	(8)	23	(19)	
Pancreas	16	(7)	14	(11)	
Rectum	4.5	(2)	14	(11)	
Bile duct	2.3	(1)	4.9	(4)	
Ovary	0		6.2	(5)	
Others	4.5	(2)	8.6	(7)	
Metastatic sites					
Lung	14	(6)	25	(20)	0.15
Pleura	18	(8)	21	(17)	0.71
Liver	43	(19)	46	(37)	0.79
Peritoneum	77	(34)	59	(48)	0.043
Complications and treatments					
Oral intake fluids <500 mL/day 1 week before death	84	(37)	52	(42)	<0.001
Vomiting	39	(17)	27	(22)	0.19
Intestinal obstruction	66	(29)	54	(44)	0.21
Intestinal drainage	30	(13)	7.4	(6)	<0.001
Ascites drainage	18	(8)	9.9	(8)	0.18
Pleural drainage	2.3	(1)	2.5	(2)	1.0
Diuretics	34	(15)	41	(33)	0.47

There were no significant differences in mean BUN/creatinine, sodium, or potassium levels between the groups.

Prevalence of Hypoalbuminemia, Prerenal Azotemia, Hyper/Hyponatremia, and Hyperkalemia in the Last Week

In the entire sample and in the subgroup of patients with oral intake of fluids <500 mL/day, the prevalence of hypoalbuminemia was significantly higher in the hydration group than in the nonhydration group (Table 4). The prevalence of hyponatremia tended to be higher in the hydration group than in the nonhydration group, both in the entire sample and in the subgroup of patients with oral intake of fluids <500 mL/day, with a marginal statistical significance. There were no significant differences in the prevalence of azotemia, hypernatremia, or hyperkalemia between the groups.

Interaction Between Hydration Group and the Changes in Albumin, BUN/Creatinine, Sodium, and Potassium Levels During the Last 3 Weeks

A total of 93 patients (74% of 125 analyzed patients) received laboratory examinations both 3 weeks and 1 week before death. There were no statistically significant differences in patient age, gender, and primary site between the

Table 3
Laboratory Findings in the Last Week

	All samples			Patients with Peritoneal Metastasis			Patients with Oral Intake Fluids <500 mL/day		
	Hydration Group ($n=44$)	Nonhydration Group ($n=81$)	P	Hydration Group ($n=34$)	Nonhydration Group ($n=48$)	P	Hydration Group ($n=37$)	Nonhydration Group ($n=42$)	P
Albumin (g/L)	2.4 ± 0.52	2.7 ± 0.50	0.005	2.4 ± 0.49	2.7 ± 0.55	0.025	2.4 ± 0.53	2.7 ± 0.50	0.005
BUN/creatinine	46 ± 20	40 ± 21	0.18	48 ± 20	40 ± 18	0.069	48 ± 20	42 ± 22	0.19
Sodium (mmol/L)	135 ± 6.4	136 ± 5.3	0.48	136 ± 6.6	135 ± 5.0	0.32	135 ± 6.6	136 ± 5.1	0.33
Potassium (mmol/L)	4.4 ± 0.72	4.4 ± 0.88	0.91	4.3 ± 0.73	4.3 ± 0.94	0.91	4.3 ± 0.72	4.3 ± 0.98	0.93

Table 4
Prevalence of Abnormal Laboratory Findingsin the Last Week

	All Samples					Patients with Peritoneal Metastasis					Patientswith Oral Intake Fluids <500 mL/day				
	Hydration Group ($n=44$)		Nonhydration Group ($n=81$)			Hydration Group ($n=34$)		Nonhydration Group ($n=48$)			Hydration Group ($n=37$)		Nonhydration Group ($n=42$)		
	%	n	%	n	P	%	n	%	n	P	%	n	%	n	P
Hypoalbuminemia (<2.0 g/L)	23	(10)	8.6	(7)	0.028	21	(7)	10	(5)	0.20	24	(9)	4.8	(2)	0.020
Prerenal azotemia*	11	(5)	6.2	(5)	0.37	12	(4)	4.2	(2)	0.39	14	(5)	7.1	(3)	0.39
Hypernatremia (>145 mmol/L)	6.8	(3)	4.9	(4)	0.70	8.8	(3)	2.1	(1)	0.31	8.1	(3)	4.8	(2)	0.66
Hyponatremia (<130 mmol/L)	27	(12)	14	(11)	0.074	21	(7)	19	(9)	0.91	27	(10)	12	(5)	0.087
Hyperkalemia (>6.0 mmol/L)		0	4.9	(4)	0.30	2.9	(1)	8.3	(4)	0.39		0	4.8	(2)	0.50

*BUN/creatinine >72.

patients who had laboratory data at the two points in time and those who had only one-point data (data not shown). Fig. 1 demonstrates that there was a statistically significant interaction between hydration group and changes in albumin level (2.8 ± 0.68 mg/dL 3 weeks before death to 2.4 ± 0.56 mg/dL 24 hours before death in the hydration group vs. 2.8 ± 0.53 to 2.6 ± 0.45 mg/dL in the nonhydration group). There were no significant interactions between the hydration group and changes in the BUN/creatinine, sodium, or potassium levels during the last 3 weeks (34 ± 15, 3 weeks before death, to 44 ± 17, 24 hours before death in the hydration group, vs. 31 ± 17 to 39 ± 20 in the nonhydration group; 134 ± 6.1 to 136 ± 6.6 mmol/L vs. 135 ± 4.7 to 136 ± 5.8 mmol/L; 4.4 ± 0.65 to 4.4 ± 0.68

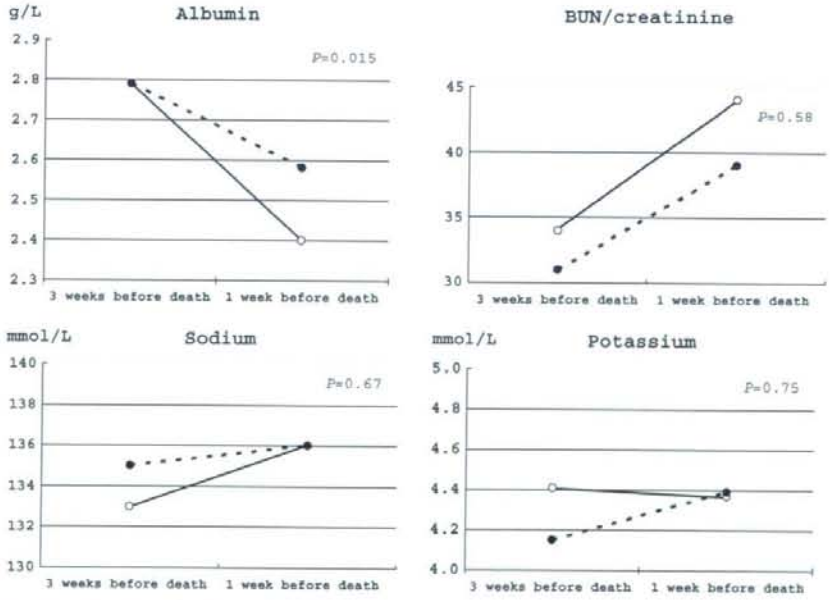

Fig. 1. Association between hydration practice and changes in laboratory findings. (○) Hydration group ($n=37$); (●) nonhydration group ($n=56$).

Table 5
Fluid Balance in the Final 3 Weeks ($n = 53$)

	3 Weeks Before Death	1 Week Before Death	24 Hours Before Death
Calculated fluid balance			
Median (range)	−400 (−1600, 757)	−521 (−1750, 493)	−421 (−2086, 1057)
Ranges			
<−1000 mL/day	9.4% ($n = 5$)	19% ($n = 10$)	13% ($n = 7$)
−1000 to −500 mL/day	38% ($n = 20$)	36% ($n = 19$)	32% ($n = 17$)
−499 to 0 mL/day	38% ($n = 20$)	34% ($n = 18$)	34% ($n = 18$)
1–500 mL/day	11% ($n = 6$)	11% ($n = 6$)	17% ($n = 9$)
>500 mL/day	3.8% ($n = 2$)	0	3.8% ($n = 2$)
Output data			
Urine volume (mean, mL/day)	951 ± 492	876 ± 478	590 ± 460
Drainage volume (median, mL/day)			
Vomiting	29 ($n = 12$)	71 ($n = 8$)	14 ($n = 7$)
Intestinal	160 ($n = 12$)	116 ($n = 12$)	127 ($n = 16$)
Ascites	214 ($n = 6$)	157 ($n = 5$)	0
Pleural effusion	286 ($n = 3$)	71 ($n = 3$)	186 ($n = 2$)

mmol/L vs. 4.2 ± 0.66 to 4.4 ± 0.91 mmol/L; respectively).

Associations Between Calculated Fluid Balance and the Changes in Clinical Signs of Dehydration and Fluid Retention

Of 113 patients who consumed 500 mL/day or less fluid intake orally throughout the last 3 weeks, 53 patients had complete fluid balance data. There were no statistically significant differences in patient age, gender, and primary site between the included and excluded patients, but the included patients were significantly more frequently recruited from oncology settings (data not shown). The percentages of patients receiving artificial hydration of 500 mL/day or more was 92% 3 weeks before death, 83% 1 week before death, and 72% 24 hours before death.

Table 5 summarizes the fluid balance data during the final 3 weeks. The percentage of patients with positive calculated fluid balance was less than 25% throughout the three study points.

The calculated fluid balance was not significantly different between the patients with deterioration in scores of dehydration, edema, ascites, and pleural effusion during the last 3 weeks and those without (Table 6). Moreover, the calculated fluid balance was not significantly linearly correlated with the changes in dehydration, edema, ascites, and pleural effusion scores ($\rho = 0.012$ and 0.93; $\rho = 0.051$ and 0.72; $\rho = 0.14$ and 0.30; $\rho = 0.085$ and 0.55, respectively).

Discussion

This is, to the best of our knowledge, the first multicenter prospective study to explore the association between artificial hydration practice and laboratory findings, as well as between fluid balance and clinical signs of dehydration and fluid retention in the last week of life in terminally ill cancer patients.

One of the important findings of this study was that active hydration was significantly associated with hypoalbuminemia. This interaction of artificial hydration with the changes in albumin levels during the last 3 weeks remained statistically significant after adjusting multiple

Table 6
Fluid Balance of the Patients With and Without Deteriorated Scores of Dehydration and Fluid Retention

	Mean (mL/day)	Median (mL/day)	*P*
Dehydration score[a]			0.79
+3 or more ($n = 11$)	−475 ± 453	−400	
+2 or less ($n = 42$)	−572 ± 547	−572	
Edema score[b]			0.87
+3 or more ($n = 20$)	−582 ± 542	−450	
+2 or less ($n = 33$)	−534 ± 524	−549	
Ascites score[c]			0.23
+1 or more ($n = 10$)	−365 ± 518	−250	
0 or less ($n = 43$)	−596 ± 524	−595	
Pleural effusion score[c]			0.14
+1 or more ($n = 5$)	−284 ± 773	93	
0 or less ($n = 48$)	−580 ± 497	−572	

[a]Calculated from three physical findings. A higher score indicates a higher level of dehydration, with possible range of 0–5.
[b]Calculated from seven physical findings. A higher score indicates a higher level of peripheral edema, with possible range of 0–21.
[c]Rated as 0 (physically nondetectable) to 2 (symptomatic).

covariates. The potential mechanism of this phenomenon includes dilution by a large amount of fluids in artificial hydration therapy, and this finding supports a clinical assumption that excessive artificial hydration could result in fluid retention through decrease in colloid osmotic pressure.[10,16,17]

The second important finding of this study was that, even when artificial hydration was not actively performed, sodium and potassium levels in the last week were within essentially normal ranges in a great majority of patients. In this study, median of calculated fluid balance was −400 mL/day or less throughout the last 3 weeks and only 20% of the patients had positive fluid balance. Nonetheless, hypernatremia and hyperkalemia were identified in less than 10% of the patients. These findings are consistent with preliminary empirical findings from hospice settings that, even in patients who received no artificial hydration, mean sodium and potassium levels were within normal ranges.[3,5,6] Therefore, it is assumed that serious sodium and potassium imbalance is not always common in terminally ill cancer patients, even if they do not receive active artificial hydration. These results suggest that the physiology of water metabolization in the terminal stage of cancer might be different from that in healthy or acute stage patients, because insensible water loss, depending on caloric expenditure, might be smaller in patients with cachexia and lower mental activity,[9,15] and/or because fluid shift could occur from the third space to the intravenous component. Physiological studies to clarify water metabolism and amount of water required for terminally ill cancer patients are strongly needed.

Of special note was that BUN/creatinine levels constantly increased in the last 3 weeks regardless of whether the patients received artificial hydration therapy or not. This finding supports a hypothesis suggested by an observational study on a small number of abdominal cancer patients that the pathophysiology of dehydration in terminally ill cancer patients is intravenous water depletion caused by fluid shift from the intravascular component to the interstitial spaces, not total body dehydration.[17] It suggests that artificial hydration therapy does not always alleviate water depletion under the condition in which administered water cannot be maintained in the intravascular component, due to increased membrane permeability and/or decreased colloid osmotic pressure.

The third important finding of this study is that calculated fluid balance was not strongly associated with changes in clinical signs of dehydration and fluid retention. This finding reflects a hypothesis that not total fluid deficit but fluid shift from intravascular components to interstitial spaces is a major factor in the development of fluid retention in terminally ill cancer patients.[17] The clinical implication of this finding is that fluid balance study is not an appropriate alternative to direct evaluation of patient symptoms.

This study clearly has multiple major limitations, and interpretation of the findings requires special caution. First, laboratory and fluid balance studies were performed according to clinical requirements, and all patients did not receive these examinations. We believe, however, that this is an acceptable limitation of this study, because clinical research designed to obtain these examinations from all terminally ill patients is practically and ethically difficult and would result in unacceptable recruitment bias, and because patient backgrounds were not significantly different between the included and excluded patients. Second, this is an observational study, and therefore contains some treatment bias. Third, study subjects were limited to those with abdominal malignancies, and thus the results might not be applicable to other patients. Fourth, because calculated fluid balance did not include actually measured insensible water loss and oral intake volume, the fluid balance data calculated in this study might be over or underevaluated. Fifth, we investigated only fluid volume, and electrolytes or calories (hyperalimentation or not) administered for each patient was not considered. Sixth, reliability of the measurement schedule adopted in this study was not formally established. Finally, the small sample size made several statistical analyses difficult and limits generalization of the conclusions.

In conclusion, active artificial hydration could result in hypoalbuminemia, with no clear beneficial effects on normalizing BUN/creatinine, sodium, or potassium levels, and fluid balance does not strongly correlate with actual changes in clinical signs of dehydration and fluid retention. Calculated fluid balance would not be an appropriate alternative to

direct monitoring of patient symptoms. More study is clearly needed to determine the role of artificial hydration therapy in the last 3 weeks for the terminally ill cancer patients.

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Appendix

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