Microwave Ablation Vs Traditional Thyroidectomy for Benign Thyroid Nodules: A Prospective, Non-Randomized Cohort Study

Shaokun Li, MD#, Mingfeng Yang, MD#, Haipeng Guo, MD, Muyuan Liu, MD, Shaowei Xu, MD, Hanwei Peng, MD, PhD

Rationale and Objectives: To evaluate the efficacy of microwave ablation (MWA) for benign thyroid nodules (BTNs) and compare trauma and complication rates between MWA and traditional thyroidectomy for BTNs.

Materials and Methods: 84 patients with BTNs were recruited and followed up at 1, 3, 6, and 12 months. 56 and 28 patients chose to undergo MWA (group A) and traditional thyroidectomy (group B), respectively. Efficacy was assessed by volume reduction rate (VRR) and therapeutic success rate (TSR) at each follow-up. Trauma was compared using inflammation response parameters, visual analog scale (VAS) scores, quality of life (QOL) and thyroid function measures at 1, 3, and 6 months. Complications rates were also compared.

Results: The VRR was 80.70 ± 18.60%, and TSR was 91.70% at 6 months. Furthermore, the VRR increased to 90.45 ± 11.51%, and TSR increased to 100% at 12 months. C-reactive protein levels were significantly higher in group B on the first postoperative day (POD) (3.89 ± 0.86 mg/mL vs 3.39 ± 0.56 mg/mL, p = 0.002). Visual analog scale scores were significantly lower in group A on the first and second POD. Thyroid stimulating hormone levels were significantly lower in group A at three (1.71 ± 1.12uIU/mL vs 2.37 ± 1.24uIU/mL, p = 0.013) and 6-months (1.34 ± 0.70uIU/mL vs 1.97 ± 0.94uIU/mL, p = 0.002). There were no significant between-group differences in QOL and complication rates.

Conclusion: Microwave ablation shows acceptable and promising efficacy. Compared with thyroidectomy, MWA was associated with less trauma and comparable complication rates.

Key Words: Microwave ablation; Thyroidectomy; Benign thyroid nodules; Trauma; Complications.

INTRODUCTION

Thyroid nodules are a common clinical problem, with a prevalence of 20% to 76% in the general population by ultrasound examination (1). Most benign thyroid nodules (BTNs) are asymptomatic and need only to be monitored over time. However, some patients with BTNs require surgical or non-surgical intervention due to compression-related symptoms or cosmetic or psychological problems. Thyroid-stimulating hormone (TSH) suppression and surgery have been the main therapeutic protocols for patients requiring intervention. The efficacy of TSH suppression is controversial due to its potential side effects (eg, increased average heart rate, increased risk of atrial fibrillation in older individuals, accelerated bone turnover in postmenopausal women) (2). Furthermore, Berghout et al. (3) reported that nine months after the withdrawal of L-thyroxine or L-thyroxine/carbimazole, thyroid nodule volume regrew to baseline levels in candidates who initially responded to the treatment. In addition, TSH suppression therapy for BTNs is not recommended in iodine-sufficient populations (4). Although traditional thyroidectomy is the mainstay management of symptomatic BTNs, its disadvantages include neck scarring and risk of complications (eg, wound bleeding, recurrent...
laryngeal nerve injury, hypoparathyroidism, and hypothyroidism). Based on a database from a multicenter audit comprising 3,660 patients who underwent thyroidectomy, Bergenfelz et al. (5) reported that 2.10% of patients experienced re-bleeding and the incidence of nerve paresis was 0.97% 6 months after. Further, 9.90% and 4.40% of patients who underwent bilateral thyroidectomy experienced hypocalcemia treated with vitamin D analog at the first follow-up and after 6 months, respectively. Puzziello et al. (6) reported that the incidence of postoperative hypocalcemia was 38.89% after near-total thyroidectomy and 28.96% after primary total thyroidectomy. Although endoscopic thyroid surgeries spare a neck scar, their limitations include longer operating time, greater postoperative pain, a steep learning curve, risk of carbon dioxide embolism, subcutaneous emphysema, and skin ecchymosis (7,8).

Consequently, minimally invasive techniques such as chemical and thermal ablation were introduced as alternatives to the management of BTNs (9). These approaches have been found to effectively reduce nodule volume and improve compression-related symptoms and cosmetic problems. Ethanol ablation is an effective and safe procedure for patients with purely or predominantly cystic nodules, which has been in use for decades (10,11). Thermal ablation techniques, including radiofrequency ablation, laser ablation, microwave ablation (MWA), and high intensity focused ultrasound have been proposed as alternative treatments for BTNs, and particularly solid or predominantly solid nodules (12-16).

Microwave ablation has been used to manage BTNs for years, with established safety and efficacy (12,13,17-20). This minimally invasive procedure has been reported to have a minimal impact on thyroid function (19,21-23). However, studies have mainly focused on its efficacy and safety and comparing the efficacy of different ablation techniques (12,13,19). A few studies have compared thyroid function preservation and/or trauma between ablation techniques and surgical interventions (21,22,24). To the best of our knowledge, no published systematic study has simultaneously compared the effects of MWA and traditional thyroidectomy for BTNs on trauma and complications. Thus, this prospective cohort study was designed to evaluate the efficacy of MWA, as well as to systematically compare differences in trauma and complication rates between MWA and thyroidectomy for BTNs.

MATERIALS AND METHODS

This study was registered at http://www.chictr.org.cn as a Non-Randomized Prospective clinical trial (ChiCTR2000041400) and approved by the Ethics Committee of the authors’ affiliation (NO. 2019014). All patients provided written informed consents prior to study enrollment.

Inclusion Criteria

Patients that met the following criteria were included: (1) BTN confirmed at least twice by ultrasound-guided fine-needle aspiration cytology (FNAC), (2) local compression symptoms and/or cosmetic or psychological problems caused by BTN, (3) appropriate candidates for both thyroidectomy and thermal ablation, (4) solid prominent nodule(s) volume <20ml, cyst prominent nodule(s) volume <30ml; (5) euthyroidism; and (6) written informed consent was available.

Patients with malignant or cytologically indeterminate nodules diagnosed by FNAC, substernal goiter, coagulation disorder, severe cardio-pulmonary dysfunction, neck radiation history, or family history of thyroid cancer were excluded. Nodules with the longest diameter of less than 1 cm were conservatively managed with watchful ultrasound follow-up rather than surgical or thermal ablation intervention.

Each patient was informed without bias by a senior surgeon, concerning treatment procedures, anesthesia, treatment purposes, expected outcome, potential complications, cost, and follow-up workup of the two procedures, and he/she was asked to choose a preferred treatment method. Consequently, a total of 84 patients were included in the study, of which 56 patients chose MWA (group A), while 28 patients chose thyroidectomy (group B).

Instruments and Preoperative Preparations

The MWA instrument was equipped with a MWA generator (highest output power = 120 W, frequency = 2450 MHz) and a disposable internal-cooled ablation antenna (MTI - 5D, ChangCheng Medical Devices Co. Ltd, Nanjing, China). An ultrasound system with a linear probe of 4-14 MHz (Esaote MyLab 30CV, BaiSheng Medical Science Co.Ltd, Shenzhen, China) was used for FNAC guidance, the ablation procedure, and preoperative and follow-up assessment of ablated nodules.

A surgeon and a senior sonographer routinely performed preoperative US evaluation of the thyroid gland, and a surgeon performed the FNAC.

Procedures

Two experienced surgeons performed the MWA procedures under US guidance. Patients with multiple target nodules underwent a single ablation session. The patient was placed in a supine position with his/her neck extended. Before ablation, the surgeon located the target nodule(s) and evaluated its (their) blood flow and anatomic relation with adjacent structures to determine the puncture site and route. An anesthetic mixture (2% lidocaine 20.0 ml + 0.1% adrenalin hydrochloride 0.3 ml + saline 30.0 ml) was administrated through middle point of posterior sternocleidomastoid muscle, which was superficial cervical plexus block. Next, a hydro-separation mixture (0.1% adrenalin hydrochloride 0.3 ml in saline 50.0 ml) was administered between the thyroid capsule and adjacent critical structures to avoid thermal damage. The output power was set at 30 W without consideration of the diameter or volume of the target nodule. The skin of the neck was punctured with a 15G syringe needle. The procedure began once the MWA antenna was inserted into the targeted
nodule through the puncture site along the designed route. A moving-shot technique was employed, and the procedure was continued until the ablated nodule(s) was/were completely covered by hyper-echoic signals. The blood flow signal was checked to confirm the completeness of the nodule ablation.

Two senior surgical teams performed the thyroidectomy procedures. Nineteen patients underwent lobectomy, and nine patients underwent bilateral subtotal thyroidectomy.

Evaluating the Efficacy of Microwave Ablation

Three orthogonal diameters of the targeted nodules were measured and used to calculate the target nodule volume (NV) using the following equation: \( \text{Nodule Volume} = \pi \times A \times B \times C / 6 \) (where \( A \) = the longest diameter, \( B, C \) = orthogonal diameters with \( A \)). Nodule volume reduction rate (VRR) was calculated using the following equation:

\[
\text{VRR} = \frac{(\text{initial volume} - \text{follow up volume})}{\text{initial volume}} \times 100\%.
\]

This was used to evaluate the efficacy of MWA. Therapeutic success was achieved when VRR > 50% (25). Further, therapeutic success rate (TSR) was used as an additional parameter to evaluate the efficacy of MWA. Nodule recurrence was defined as the new blood flow in the ablative area and / or > 50% nodule volume increase. Nodule recurrence was recorded if occurred.

Evaluation of Treatment Trauma

The inflammation response was evaluated using serum levels of C-reactive protein (CRP), interleukin-6 (IL-6), and pro-calcitonin (PCT) at baseline and the first postoperative day (POD). The wound pain was assessed by a 10-point visual analog scale (VAS), where 0 represented no pain and 10 represented the most severe pain. Visual analog scale scores were recorded at baseline and the 1st and 2nd POD. In addition, the EORTC QLQ-C30 questionnaire (Chinese version) (26) was used to evaluate the quality of life (QOL). This questionnaire is comprised of 30 items spanning five functional subscales (i.e., physical function, role function, emotional function, cognitive function, and social function) and a global health status subscale. Higher scores indicate better QOL. Patients were instructed to fill out the questionnaire preoperatively and at 1, 3, and 6 months. Total scores were compared across time points. Furthermore, thyroid function parameters, including TSH, total triiodothyronine (TT3), and total thyroxine (TT4) were also measured at baseline and 1, 3, and 6 months.

Complications

Complications related to MWA or thyroidectomy were recorded during the hospital stay and carefully monitored at follow-ups. Both minor and major complications were recorded according to the Society of Interventional Radiology Clinical Practice Guidelines Classification System (27).

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, N.Y.). GraphPad Prism version 8.0 for Windows (GraphPad Software, San Diego, C.A.) was used to create figures. Volume reduction rates, VAS scores, and trauma parameters were expressed as means ± standard deviations. Categorical variables were expressed as frequencies and percentages. Quantitative variables were compared using the Mann-Whitney U test, and categorical variables were compared using Fisher’s exact test. A significant difference was considered when \( p < 0.05 \).

RESULTS

Demographic Data and Baseline Characteristics

A total of 84 patients with 109 nodules were included in the study. In group A, there were 56 patients with 72 targeted nodules; 48 were females and 8 were male; the median age was 44 ± 12 (range, 13 - 71) years; ten patients (17.85%) had multiple nodules; the average nodule volume was 8.35 ± 6.91ml; 25 nodules (34.72%) were prominently solid which was defined when the solid component constitutes estimated more than 70 percent of the whole nodule. In group B, there were 28 patients with 37 nodules, including 25 females and 3 males, with a median age of 38 ± 14 (range, 13 - 68) years; 6 patients (21.43%) had multiple nodules; the average nodule volume was 8.27 ± 8.96ml; fifteen nodules (40.54%) were prominently solid. Beside demographic data, the baseline characteristics including nodule number, nodule size, nodule consistency, inflammation biochemical markers, VAS scores, QOL scores, and thyroid function were shown in (Table 1). Statistical analysis showed that all these parameters were comparable between the 2 groups.

Treatment Efficacy

Treatment efficacy was evaluated for 72 nodules in 56 patients in group A. The patients were followed at 1, 3, 6, and 12 months after MWA. Average NVs, VRRs, and TSRs are displayed in (Table 2). The VRR was 80.70 ± 18.60%, and TSR was 91.70% at 6-months. Furthermore, the VRR increased to 90.45 ± 11.51%, and TSR increased to 100% at 12-months. No nodule recurrence was recorded within 12 months.
Average serum CRP, IL-6, and PCT levels were elevated at the first POD compared with baseline. Statistical analysis revealed that CRP levels were significantly higher in group B than in group A at the first POD (3.89 ± 0.86 mg/mL vs 3.39 ± 0.56 mg/mL, p = 0.002) (Fig. 1a). There were no significant between-group differences in IL-6 or PCT levels at the first POD (2.53 ± 0.86 pg/mL vs 3.11 ± 1.48 pg/mL, p = 0.137; 0.032 ± 0.015 ng/mL vs 0.041 ± 0.031 ng/mL, p = 0.374) (Fig. 1b, 1c).

Table 3 presents patients’ VAS scores. These scores were significantly lower in group A than in group B at the first and second POD. 

Average QOL subscale scores are shown in (Fig. 2a – 2f). The average scores of all of the subscales displayed a downward trend or were stable at one month and increased at three and six months. However, there were no significant between-group differences in the average subscale scores at any of the follow-up time points.

The TSH levels were significantly lower in group A than in group B at 3 (1.71 ± 1.12uIU/mL vs 2.37 ± 1.24uIU/mL, p = 0.013) and 6 months (1.34 ± 0.70uIU/mL vs 1.97 ± 0.94uIU/mL, p = 0.002). Further, there was a borderline between-group difference in TSH levels at 1 month (1.28 ± 0.62uIU/mL vs 1.77 ± 1.05 uIU/mL, p = 0.050) (Fig. 3a). There were no statistically significant differences in TT3 and TT4 levels at any of the follow-up time points (Fig. 3b, 3c). None of the patients in either group required levothyroxine for thyroid dysfunction.

Complications

The complications that occurred in both groups are listed in (Table 4). Three patients in group A developed non-infectious nodule ruptures that were cured without leaving a recognizable scar after 4-to-6 weeks of drainage and wound care (Fig. 4a – 4c). In both groups, all minor complications resolved spontaneously within 1-to-2 months without any intervention. There were no significant between-group differences in the rates of major or minor complications (p_major = 0.547, p_minor = 0.661).

DISCUSSION

Although there is a high incidence of BTN in the general population, only symptomatic BTN require surgical or non-

| TABLE 1. Demographic Data and Baseline Characteristics of the Series |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
|                            | Group A (n = 56)            | Group B (n = 28)            | p                          |
| Age [median±SD (range)]    | 44 ± 12 (13 - 71)          | 38 ± 14 (13 - 68)          | 0.214                      |
| Female [pt. n (%)]         | 48 (87.50)                | 25 (89.29)                 | 0.744                      |
| Solid nodules [nodule n (%)] | 25 (34.72)              | 15 (40.54)                 | 0.675                      |
| Multiple nodules [pt. n (%)] | 10 (17.86)               | 6 (21.4%)                  | 0.771                      |
| Nodule volume (mL)        | 8.35 ± 6.91               | 8.27 ± 7.09                | 0.961                      |
| CRP (mg/L)                | 3.19 ± 0.45               | 3.13 ± 0.71                | 0.137                      |
| IL-6 (pg/mL)              | 2.24 ± 0.59               | 2.23 ± 0.72                | 0.538                      |
| PCT (>10 ng/mL)           | 0.32 ± 0.13               | 0.30 ± 0.12                | 0.732                      |
| VAS score                 | 0.09 ± 0.29               | 0.11 ± 0.32                | 0.794                      |

QOL subscales

- Physical function
  - Group A: 95.48 ± 9.18
  - Group B: 96.67 ± 6.41
- Role function
  - Group A: 98.51 ± 5.75
  - Group B: 95.24 ± 11.88
- Emotional function
  - Group A: 86.01 ± 16.14
  - Group B: 80.06 ± 17.17
- Cognitive function
  - Group A: 86.31 ± 15.60
  - Group B: 87.50 ± 17.35
- Social function
  - Group A: 88.39 ± 16.79
  - Group B: 92.86 ± 15.34
- Global health status
  - Group A: 73.66 ± 19.51
  - Group B: 71.4 ± 21.92

TSH (uIU/mL)

- Group A: 1.39 ± 0.77
- Group B: 1.25 ± 0.56

TT3 (nmol/L)

- Group A: 1.79 ± 0.26
- Group B: 1.71 ± 0.26

TT4 (nmol/L)

- Group A: 128.70 ± 17.38
- Group B: 127.25 ± 13.81

CRP, C reactive protein; IL-6, interleukin-6; PCT, procalcitonin; QOL, quality of life; TSH, thyroid stimulating hormone; TT3, triiodothyronine; TT4, thyroxine; VAS, visual analog scale; pt., patient.

| TABLE 2. Efficacy Outcomes in Patients that Underwent Microwave Ablation |
|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Outcome                    | Baseline                    | 1 Month                     | 3 Months                    | 6 Months                     | 12 Months                    |
| Average NV (ml)            | 8.35 ± 6.91                 | 4.43 ± 4.14                 | 2.73 ± 2.90                 | 1.62 ± 2.11                  | 0.90 ± 2.00                  |
| Average VRR (%)            | NA                          | 43.2 ± 33.1                 | 67.5 ± 23.1                 | 80.7 ± 18.6                  | 90.45 ± 11.51                |
| TSR (%)                    | NA                          | 48.6                        | 80.6                        | 91.7                         | 100                          |

NA, not applicable; NV, nodule volume; TSR, therapeutic success rate; VRR, volume reduction rate
The main purpose of MWA is to debulk the nodules and relieve symptoms rather than completely remove the nodules. Microwave ablation has been found to be effective and safe in treating BTNs. Volume reduction rates have been reported to range from 65.00% to 81.00% at 6 months and from 79.60% to 92.40% at twelve months. Therapeutic success rates have been reported to range from 82% to 97% at 6 months and from 93% to 100% at 12 months. In our study, we found that the average VRRs and TSRs were 80.70% and 91.70% at 6 months, respectively, and increased to 90.45% and 100%, respectively, at 12 months. These findings were similar to the results reported by other authors.

Cheng et al. (13) reported that although most nodules did not completely disappear after MWA, the mean symptomatic and cosmetic scores at the last follow-up significantly decreased compared with before MWA, indicating that compression symptoms were relieved and cosmetic problems were improved. Our study did not evaluate patients’ symptomatic or cosmetic scores. However, all patients were satisfied with the treatment, and none required further intervention. Wang et al. (31) reported that being adjacent to important tissues might be associated with an increased risk of recurrence of benign non-functioning thyroid nodules due to the inadequate thermal ablation resulting from the fear of vital structure damage. However, no recurrence of the ablated nodules was found at the final follow-up in the current series, which might due to the hydro-separation technique used to provides a secure zone for better thermal ablation while avoid injury to adjacent structures.

Microwave ablation was hypothesized to be a minimally invasive and safe procedure with better protection of thyroid function for BTNs, as compared with traditional thyroidectomy. In verifying this hypothesis, we conducted a non-randomized cohort study to evaluate and compare between-group outcomes across four dimensions, including inflammation biomarkers (ie, CRP, IL-6, PCT), pain (ie, VAS scores), QOL, and thyroid function.

Several studies have investigated the inflammation caused by MWA and traditional thyroidectomy, mainly through laboratory biomarkers, including CRP, IL-6, IL-8, TNF-α, and WBC counts. Baseline CRP level elevation is associated with infection and tissue injury; after the onset of inflammation or tissue injury, serum CRP concentration may increase 1000-fold within 48 hours. IL-6 regulates immune responses, acute phase responses, and inflammation.
levels of PCT in patients who were in a normal postoperative course without inflammation or infection depended on surgery type. Therefore, serum levels of CRP, IL-6, and PCT were chosen as inflammation biomarkers to reflect the trauma caused by MWA or thyroidectomy. Yan et al. (22) reported that compared with MWA, open surgery was associated with significantly higher serum levels of high sensitive CRP and IL-6 at all postoperative time points (8, 24, and 48 hours). Liu et al. (21) reported that IL-6 levels were higher in the surgical vs. MWA group 6, 24, and 72 hours after operation. Our study found that on the first POD, CRP levels were significantly higher in group B than in group A. In contrast, no significant between-group differences were found in IL-6 or PCT levels on the first POD. These results indicate that MWA was associated with milder trauma than thyroidectomy. Possible explanations for the lack of significant differences in IL-6 and PCT levels include the limited sensitivity of these biomarkers and our study’s small sample size. Further, a single serum level measurement of these biomarkers may lead to the omission of more information, if existed.

The VAS score is a subjective parameter associated with trauma. Patients’ VAS scores on the 1st and 2nd PODs were significantly lower in group A than in group B. This may be interpreted to mean that MWA is characterized by a milder trauma and a more rapid recovery, physiologically and/or psychologically.

The QLQ-30 was the third parameter used to evaluate the trauma associated with the procedures. The validity of the QLQ-30 Chinese version has been established elsewhere. Zhi et al. (28) used a similar questionnaire, the HRQOL 36-Item Short Form Survey (SF-36), to evaluate patients’ QOL. They reported that compared with patients who underwent surgery, patients underwent MWA had better general health and mental health scores at 6 and 12 months. Our study found that the average scores of all QOL subscales showed a downward or stable trend at one month and increased at three and six months. However, no statistically significant differences were found in the QOL subscale scores between the two groups. These results imply that both MWA and...
thyroidectomy had a limited impact on patients’ QOL and the impacts were reversible within 6 months.

Another potential advantage of MWA is better protection of thyroid function due to its accurate ablation of the targeted nodules with minimal injury to the adjacent thyroid tissue (35). Liu et al. (21) revealed that TSH levels in the surgery group were higher, and FT4 and FT3 levels were lower than in the MWA group at 3 and 6 months. In our study, TSH levels were significantly lower in group A than in group B at 3 and 6 months, and there was a borderline between-group difference in TSH levels at one month. However, there were no statistically significant differences in TT3 or TT4 at any of the follow-up periods. None of the patients in either group required levothyroxine replacement. Collectively, these results indicate that thyroid function was more stable in group A than in group B. Both procedures had a limited impact on thyroid function.

Microwave ablation has been reported to be a safe procedure for BTNs. Similar to other studies, we did not find a significant between-group difference in the incidence of both major and minor complications. No permanent recurrent laryngeal nerve palsy or permanent hypoparathyroidism was recorded, which demonstrated both MWA and thyroidectomy are safe interventions for BTNs. However, as reported by previous studies, we found that MWA was associated with nodule rupture (36-38). In our study, nodule ruptures developed in 3 patients with an incidence of 5.36% (3/56). Nodule ruptures were determined to be aseptic based on the negative results of pathogen cultures in all 3 cases and cured without leaving recognizable scars by four-to-six weeks of drainage and wound care. Interestingly, nodule ruptures developed exclusively in patients with solid prominent nodules in our series. All patients complained of a sudden bulging and pain or discomfort in the ablation area one to two weeks after ablation. The possible mechanism of nodule rupture was supposed to be associated with delayed hemorrhage occurs in the post-ablation nodules, which may be caused by micro-vessels leakage at the edge of the nodules. Additionally, sudden severe cough, sneeze, hiccups, forced pressure and other external factors increase the inner pressure of the nodule may lead to the post-ablation nodule rupture. Different from other reports (37,38), we advocate early intervention to prevent potential complications, eg, secondary wound infection and life-threatening tracheal or esophageal perforation. However, limited by the small study sample, further studies are needed to reveal the pathogenic mechanism of nodule rupture resulting from MWA and its prevention and appropriate management.

There were several limitations in this study. First, this was a single non-randomized cohort study. Second, the number of recruited patients was small, especially in group B. In addition, the follow-up period was not long. Multicenter, randomized, large-scale and long-term follow-up studies should be performed to further compared MWA and traditional thyroidectomy.
Based on the results of our study, we conclude that MWA shows acceptable and promising efficacy. Compared with thyroidectomy, MWA was associated with less trauma and comparable complication rates.

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Figure 4. A typical nodule rupture occurring in a patient that underwent MWA. (A). After 2 weeks, a redness was found at the neck of the patients who underwent MWA; (B). The redness was cut and drained; (C). After 3 weeks, no recognizable scar was left on the neck after wound care. MWA, microwave ablation. (Color version of figure is available online.)