A randomised trial of a geriatric evaluation and management consultation services in frail hospitalised patients

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Abstract

Background: the usefulness of geriatric evaluation and management (GEM) approaches in the care of frail elderly patients remains uncertain. We examined whether an inpatient geriatric consultation service might be beneficial in a country with a social welfare system.

Methods: we conducted a randomised trial with 345 patients from five centres. Ninety additional patients from four separate centres without GEM teams served as an external comparison. All patients were hospitalised, at least 65 years and frail. Patients were randomly assigned to either comprehensive geriatric assessment and management in the form of consultations and follow-up or usual care. Primary outcomes were rehospitalisation and nursing home placement 1 year after randomisation. Secondary outcomes were survival, functional, emotional and cognitive status, social situation and quality of life.

Findings: at 12 months, the groups did not differ in the rate of rehospitalisation (intervention 67%, control 60%, P = 0.30), nursing home placement (intervention 19%, control 14%, P = 0.27), survival (intervention 81%, control 85%, P = 0.56) or any of the other secondary measures. The external comparison groups were also similar in nursing home placement (16%, P = 0.40), survival (80%, P = 0.88) and all the secondary variables, but rehospitalisation was less (48%, P = 0.04). No subgroup benefited from the intervention.

Interpretation: care provided by consultation teams did not improve the rates of rehospitalisation or nursing home placement. This is not due to carry-over effects of geriatric knowledge into the control group.

Keywords: geriatric consultation, inpatient, acute care, elderly

Introduction

A multidisciplinary geriatric evaluation and management (GEM) approach has evolved over recent years to improve the care of frail elderly inpatients with complex conditions. In these programmes, the specialist team assesses targeted patients in a standardised way, recommending and continuously re-evaluating a treatment and discharge plan. Two different models are dedicated: inpatient GEM units (GEMU) and inpatient geriatric consultation services. In general, dedicated inpatient units have shown benefits on mortality, hospital readmission and nursing home placement [1–5], whereas consultation services have less effect [1, 6]. Recent US-based multicentre trials [5, 6] have demonstrated less effect compared with single-site European trials [2–4].

Differences between health care systems might be responsible for the inconsistent results. Furthermore, in randomised studies, a 'contamination effect' may occur if 'control' staff adopt 'intervention' management principals after seeing them practised elsewhere [7].

We conducted a randomised, multicentre clinical trial in a country with a social welfare health care system to examine the effects of comprehensive assessment and management by an inpatient consultation service on rehospitalisation, living location, survival, health status and the subjective well-being of hospitalised, frail, elderly patients. We hypothesised a reduced rate of rehospitalisation and nursing home placements within 1 year after randomisation for the intervention as compared with the control group. An external

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comparison group was recruited to examine possible contamination effects.

Methods

In 1994, specialised GEM teams (geriatrician, social worker, nurse and optionally other paramedical staff), financed by medical insurance funds, were introduced in many hospitals in south-western Germany. Five hospitals with at least 3 years' experience of providing a consultation service took part in a randomisation trial (four internal medicine and one psychiatry). In addition, four separate hospitals without consultation services formed an external comparison group (three medicine and one psychiatry). Patients were enrolled for the study between 1 July 1997 and 31 December 2000, and follow-up lasted 1 year. The study was approved by the local ethics committee. All patients gave written informed consent before enrolment.

Patients and randomisation

The consultation service physician at each centre identified patients who met the following eligibility criteria: at least 65 years, expected length of stay of at least 8 days (to allow proper evaluation and implementation of recommendations, treatment and discharge planning) of functional impairment and potential breakdown of the home situation.

Patients who met two or more of the criteria proposed by Lachs *et al.* [8] were considered to be functionally impaired. Patients were excluded if they were admitted from a nursing home, had previously been hospitalised in a GEM inpatient unit, had a terminal condition or severe dementia, did not speak German, were living beyond a 60 km radius of the coordinating centre (for study follow-up home visits), would not need help at home or could not give informed consent. Depending on their primary diagnosis, patients were admitted to general medical or psychiatric units.

New patients were screened consecutively whenever a GEM treatment place became available in the respective centre. Enrolled patients were randomly assigned to the GEM intervention group or received usual inpatient care. Assignment to groups was performed within 2 days of hospitalisation. Patients from the external comparison group were recruited from four centres and comprised consecutive eligible patients.

Baseline data and interventions

Participants were assessed by a research physician who collected baseline data using standardised, multidimensional assessment instruments within 3 days after randomisation [9]. The instruments and data collected are listed in Table 1.

Table 1. Baseline characteristics and assessment instruments according to study group

	Baseline (study population)*				
Variable	GEM group ($n = 105$)	Control group ($n = 129$)	Comparison group ($n = 81$)		
Age (years)	79.0 ± 6.9	78.4 ± 6.9	76.9 ± 7.5		
Sex (female: male)	99:51	94:35	61:20		
Height (cm)	163.6 ± 9.1	163.1 ± 8.8	162.6 ± 8.9		
Weight (kg)	65.5 ± 13.4	66.3 ± 12.2	66.6 ± 10.9		
Geriatric screening (points) [8]	6 (5–8)	6 (5–7)	5 (4–7)		
At least one hospitalisation in past year (%)	59 (39.3)	39 (29.4)	27 (33.3)		
	MV 2 (1.3)	MV 2 (1.6)	MV 0		
Index hospitalisation (days)	24 (18–34)	22 (17–33)	22 (14-42)		
Quality of Life Philadelphia Geriatric Centre Morale Scale (points) [11]	8 (6–10)	8 (7–10)	8 (5–10)		
ADL (points) [15]	73 (45–95)	80 (55–90)	90 (70–100)		
Motility index (points) [16]	18 (12–24)	18 (13–22)	22 (14–26)		
Timed-Up-And-Go-Test (sec) [17]	20 (16-31)	19 (14-30)	15 (12–23)		
Mini-Mental State Examination (points) [18]	24 (20-27)	25 (22–27)	25 (22–27)		
Geriatric Depression Scale (points) [19]	5 (3–8)	4 (2–8)	5 (3–7)		
Brief Psychiatric Rating Scale (points) [20]	28 (25-34)	29 (24.5–33)	28 (24–32)		
Montgomery Asberg Depression Rating Scale (points) [21]	11 (6–18)	9 (5–15)	11 (6–17)		
Social situation (points) [9]	17 (15–20)	19 (17–21)	19 (16.5–21)		
Social situation subscore: social contacts (points)	5 (4–6)	5 (5–6)	5 (4–6)		
Social situation subscore: social activities (points)	2 (1–3)	3 (2-4)	3 (2-4)		
Social situation subscore: living conditions (points)	9 (7–11)	9 (8–10)	9 (8–10)		
Social situation subscore: economic situation (points)	2 (1–3)	2 (1–3)	2 (1–2.5)		
Money counting test passed $[n (\%)]$ [22]	62 (41.3)	57 (44.2)	38 (46.9)		
Recognition of time test passed $[n (\%)]$ [2]	134 (89.3)	117 (90.7)	76 (93.8)		
Telephone test passed $[n (\%)]$ [2]	121 (80.7)	106 (82.2)	71 (87.7)		
Hand grip (kPa)	52 (40-65.5)	50 (36-64)	55 (40–65)		
Hearing unimpaired, with hearing aid $[n (\%)]$	111 (74.0)	94 (72.9)	60 (74.1)		
Vision unimpaired, with glasses (≥ 0.5) [n (%)]	79 (52.7)	76 (58.9)	44 (54.3)		
Use of wheelchair $[n (\%)]$	8 (5.3)	5 (3.9)	4 (4.9)		

GEM, geriatric evaluation and management; ADL, activities of daily living.

Continuous variables are expressed as mean value \pm SD or as median and quantiles depending on their distribution. Discrete variables are expressed as counts and percentages of the whole population. Missing values are marked as MV.

^{*}None of the variables differed significantly between GEM and control or GEM and comparison groups.

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If the patient was unable to provide information about the social situation or was unreliable due to cognitive impairment, information from relatives or another close person was obtained. Ward staff, the research physician and patients were aware of group assignment. Baseline data for the intervention group were made available to the consultation service. For the control and comparison groups, baseline data were not available to medical staff.

The consultation service teams comprised a social worker, nurse and physician. The geriatrician summarised problems and recommendations in a structured treatment note [10]. Team conferences were held at least weekly, with 20 min spent on each new patient and 20 min on follow-up of previously assessed patients. Treatment was evaluated, and the implementation of recommendations was appraised. Recommendations were implemented by either the consultation team, the other staff members, the patient, the proxy or the general practitioner (GP). Special attention was given to discharge and follow-up procedures. The consultation team could implement recommendations themselves if necessary, especially social work interventions (because of limited resources in standard care). When necessary, the nurse or social worker visited the patient's home together with a relative to appraise living conditions. Family members were informed about the patient's disease, disabilities and recommendations. The GP was contacted about the recommendations by the consultation service physician shortly before discharge. Community services received a detailed and structured recommendation plan and were contacted by telephone before discharge. The only additional outpatient procedure for the intervention group was a follow-up call to the patient and/or relatives by the social worker 2 weeks after discharge, who, when necessary, provided brief, limited further support in the form of a telephone consultation.

Treatment and study procedures were described in detail in a handbook. Before and annually during the study, the study chairman reviewed and visited the centres to verify their conformity to the programme and to ensure compliance with the protocol.

Patients in the control and external comparison groups received all appropriate hospital services except those provided by the consultation team. Treatments in the control group were coded (according to [10]) by a research physician using case notes. Whether recommendations were implemented was derived also from the notes and from interviewing patients and relatives.

Outcomes

Follow-up data were obtained 3 and 12 months after randomisation. The primary outcomes were living location (own home versus nursing home) and rehospitalisation rate (percentage of patients with at least one rehospitalisation and number of days in hospital) 12 months after index hospitalisation. The 3 month' and 12 month' follow-up data were collected by a research physician or by trained research assistants who were blind regarding group assignment of the patients. At 3 months, the quality of life [Philadelphia Geriatric Centre Morale Scale (PGCMS) [11]] scale was sent

to the patient. To record formal and informal care, we sent a form to the relatives. All other 3 month' follow-up data were obtained by telephone call to the patients' GP and relatives. At 12 months, functional, cognitive and emotional status and quality of life were assessed by examining the patient at home. The social situation and hours of formal and informal care provided were obtained from the patient and proxy by interview.

Statistical analyses

The sample size was set to detect a 50% reduction in the frequency of patients residing in nursing homes and a 50% reduction in the rehospitalisation rate, requiring 214 patients for each group if the assumed frequency of control group patients moving to nursing homes was 20%, the rehospitalisation rate 30%.

We compared proportions and relative risks for the main outcomes. Analyses involved all randomised patients with the exception of patients who withdrew their consent. Owing to very strict data protection laws in Germany, data from patients who withdrew their consent had to be deleted completely. We however performed a sensitivity analysis using the dropout numbers to investigate possible biases resulting from this. People who died during follow-up were treated as 'last observation carried forward' (Figure 1, available as supplementary data on http://www.oxfordjournals.org).

To control for confounding and interaction, we performed logistic regression analyses for the two primary outcomes. These models first identified prognostic factors with effects on the rate of admission to nursing homes or rehospitalisation. First, a multivariate model was computed, including all variables with not more than 10% of patients' missing values and a minimum of 5% of patients remaining in the risk group of the respective variable. These prognostic factors were age ≥80, male sex, hospitalisation in past year ≥1, geriatric screening ≥6, Mini-Mental State Examination (MMSE) <20, Brief Psychiatric Rating Scale (BPRS) ≥35, Montgomery Asberg Depression Rating Scale (MADRS) ≥11, social situation subscore: housing <9, social situation subscore: social activities <3, psychiatric patients and GEM intervention group. The final model was the result of a stepwise backward procedure based on the full model including the intervention and every prognostic factor with an entry level of P<0.1. In the third step, the remaining prognostic factors were controlled for interaction with the intervention to identify subgroups that might display differential effects for the intervention.

Results

During the enrolment period, 12,136 patients were at least 65 years of age and stayed at least 8 days in hospital. Of these, 435 (3.6%) were enrolled in the study, 175 in the intervention, 170 in the control and 90 in the external comparison group (Figure 1, available as supplementary data on http://www.oxfordjournals.org). Psychiatric patients comprised 23% in the intervention group, 28% in the control group and 17% in the external comparison group. After excluding patients who withdrew consent, follow-up was

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available on 150 (86%) in the intervention group and 129 (76%) in the control group. At baseline, intervention, control and comparison groups were similar (Table 1).

For 126 patients in the intervention group and 108 patients in the control group, the first primary outcome, 'rehospitalisation', could be obtained. Using the intention-to-treat analysis, 84 (56.0%) in the intervention and 65 (50.4%) in the control group were readmitted [relative risk 1.11, 95% confidence interval (95% CI) 0.91–1.35, P=0.31]. For128 patients in the intervention group and 111 patients in the control group, 'living location' could be obtained. Twenty-four (18.8%) in the intervention and 15 (13.5%) in the control group were staying in nursing homes (relative risk 1.39, 95% CI 0.77–2.51, P=0.28; see Table 2). Eighty-one percent of the intervention group and 85% of the control group were

alive after 12 months (relative risk of death 1.16, 95% CI 0.69-1.98, P=0.56) (Table 2). Measures of functional and health status, quality of life, care provided and outpatient consultations at 3 and 12 months showed no differences between the groups (although all randomised patients had more readmissions than the external comparison group).

A sensitivity analysis in which 'best case' and 'worst case' assumptions were made about participants who withdrew did not alter the conclusions.

In a logistic regression model, an increased risk of rehospitalisation was found for low depression (MADRS < 11; OR 0.56, CI 0.32–0.98, P = 0.04) and high geriatric screening score (>6; OR 2.04, CI 1.16–3.62, P = 0.01). Dementia (MMSE < 20; OR 6.47, CI 2.42–17.28, P = 0.0002), few social contacts (subscore social contacts <5; OR 2.13, CI

Table 2. Follow-up data at 3 and 12 months according to study group

	3 months (3 months follow-up population (with interview))*			12 months*			
Variable	GEM group $(n = 122)$	Control group $(n = 107)$	Comparison group ($n = 60$)	GEM group	Control group	Comparison group	
				Study population			
				N = 150	n = 129	n = 81	
Patients with at least one rehospitalisation (%) Rehospitalisation (days) Living location: nursing home [n (%)] Survival [n (%)]				56.0 20 (0–36) 24 (16.0) 122 (81.3)	50.4 14 (0–36.5) 15 (11.6) 109 (84.5)	37.0** 0 (0–28) 13 (16.0) 66 (81.4)	
					pulation (with i		
				n = 83	n = 78	n = 29	
Informal care (relatives and neighbours) (h/week) Institutionalised care (h/week) Quality of Life Philadelphia Geriatric Centre Morale Scale (points) [11] ADL (points) [15] Motility index (points) [16] Timed-Up-And-Go-Test (sec) [17] Mini-Mental State Examination (points) [18] Geriatric Depression Scale (points) [19] Brief Psychiatric Rating Scale (points) [20] Montgomery Asberg Depression Rating Scale (points) [21] Social situation (points) [9] Social situation subscore: social contacts (points) Social situation subscore: living conditions (points) Social situation subscore: economic situation (points) Money counting test passed [n (%)] [22]	8.5 (0.3–28) 0 (0–2.8) 7 (6–10)	8.1 (0–32.4) 0.5 (0–3.5) 8 (6–9)	6.0 (0–20) 0 (0–3.5) 8 (7–9)	10 (1–28) 0 (0–3) 8 (7–9) 90 (60–95) 16 (10–24) 20 (13–28) 25 (22–28) 3 (1–8) 26 (22–31) 6 (3.5–11) 19 (16–20) 6 (5–6) 3 (2–4) 8 (8–9) 2 (1–3) 38 (45.8)	10 (0–26) 0 (0–7) 8 (7–10) 95 (65–100) 23 (11–28) 16 (11–21) 26 (22–28) 3 (1–6) 24 (21–28) 6 (4–11) 19 (18–20) 6 (5–6) 3 (2–4) 8 (7–9) 2 (1–3) 48 (61.5)	6.5 (0–23) 1.5 (0–5) 8 (6–9) 95 (80–95) 15 (10–28) 17 (10–25) 24 (21–28) 3 (1–5) 22 (20–26) 5 (2–8) 18 (16–20) 6 (4.5–6) 3 (2–4) 9 (8–9) 2 (1–3) 17 (58.6)	
Recognition of time test passed [n (%)] [2] Telephone test passed [n (%)] [2] Hand grip (kPa) Hearing unimpaired, with hearing aid [n (%)] Vision unimpaired, with glasses (≥0.5) [n (%)] Use of wheelchair [n (%)] Outpatient doctor consultations (number) Drugs prescribed (number)				67 (80.7) 56 (67.5) 49 (35–61) 60 (72.3) 31 (37.5) 10 (12.0) 19 (11–30) 5 (4–7)	68 (87.2) 60 (76.9) 50 (30–60) 62 (79.5) 42 (53.9) 8 (10.3) 20.5 (12–34) 5 (4–7)	23 (79.3) 20 (69.0) 49 (25–70) 26 (89.7) 16 (55.2) 3 (10.3) 24 (14.5–30) 6 (4–7)	

GEM, geriatric evaluation and management; ADL, activities of daily living.

Continuous variables are expressed as mean value \pm SD or as median and quantiles depending on their distribution. Discrete variables are expressed as counts and percentages of the whole population.

^{*}None of the variables differed significantly between GEM and control or GEM and comparison groups (**except 'Patients with at least one rehospitalisation' between GEM and comparison group, P < 0.05).

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Table 3. Number and percentage of patients with at least one recommendation in each category for the intervention group and in the control group, coded according to [10]

	Intervention group ($n = 150$)			Control group ($n = 129$)			
Recommendations	Not Recommendat		Recommendation partly or not implemented	Not recommended	Recommendation implemented	Recommendation partly or not implemented	
Diagnostic evaluation/monitoring [n (%)]	14 (9.3)	134 (89.3)	2 (1.3)	12 (9.3)	114 (88.4)	3 (2.3)	
Physician referral for evaluation $[n (\%)]$	67 (44.7)	75 (50.0)	8 (5.3)	80 (62.0)	45 (34.9)	4 (3.1)	
Non-physician evaluation/management $[n \ (\%)]$	34 (22.7)	108 (72.0)	8 (5.3)	39 (30.2)	85 (65.9)	5 (3.9)	
Medication adjustment $[n (\%)]$	14 (9.3)	131 (87.3)	5 (3.3)	17 (13.2)	104 (80.6)	8 (6.2)	
Condition-specific interventions (devices, aids and procedures) $[n \ (\%)]$	67 (44.7)	81 (54.0)	2 (1.3)	54 (41.9)	73 (56.6)	2 (1.6)	
Disposition/discharge planning [n (%)]	37 (24.7)	95 (63.3)	18 (12.0)	34 (26.4)	92 (71.3)	3 (2.3)	
Home health $[n (\%)]$	122 (81.3)	13 (8.7)	15 (10.0)	110 (85.3)	8 (6.2)	11 (8.5)	
Advance directives $[n (\%)]$	137 (91.30)	13 (8.7)	0	127 (98.50)	1 (0.8)	1 (0.8)	
Community services [n (%)]	139 (92.7)	5 (3.3)	6 (4.0)	121 (93.8)	3 (2.3)	5 (3.9)	
Financial support [n (%)]	147 (98.0)	3 (2.0)	0	128 (99.2)	1 (0.8)	0	
Respite/caregiver services [n (%)]	140 (93.3)	6 (4.0)	4 (2.7)	126 (97.7)	2 (1.6)	1 (0.8)	
Counselling/professional services $[n (\%)]$	127 (84.7)	22 (14.7)	1 (0.7)	117 (90.7)	11 (8.5)	1 (0.8)	
Education [n (%)]	39 (26.0)	108 (72.0)	3 (2.0)	30 (23.3)	97 (75.2)	2 (1.6)	

0.91-5.02, P=0.08) and index hospital stay in psychiatric wards (OR 2.54, CI 1.10–5.86, P=0.03) were found to be risk factors for nursing home placement. No interactions with intervention were found for these factors. Thus, no subgroups could be shown to benefit from the consultation service.

To explore why GEM failed to provide health benefits, we examined the number of the teams' recommendations (coded according to [10]) per patient and the rate of implementation separately for the intervention and control groups. In summary, the recommendations and their rate of implementation in the two groups were comparable (Table 3).

Discussion

In this multicentre, randomised clinical trial, we sought to determine whether frail, elderly inpatients could benefit from a multidisciplinary comprehensive inpatient geriatric consultation service in terms of rehospitalisation rate, nursing home placement and survival.

We found no differences between the intervention and control groups on rehospitalisation rate, nursing home placement, survival, quality of life, functional and mental status at 3 and 12 months. Prognostic factors which have been identified previously and which were used in similar studies [6, 12, 13] were analysed for potential effects on the primary outcomes but showed no interactions with the intervention. Additionally, no clear difference in outcomes between the control group and the external comparison group was observed, suggesting that there was no 'contamination effect'. These findings are consistent with the results of a similar recent multicentre US study [6].

What are the possible explanations for the ineffectiveness of Inpatient Geriatric Consultation Service in our and the other multicentre trials [1, 6]?

First, it might be that usual care is already similar to the programmes of GEM, in contrast to some earlier studies. To our knowledge, this is the first consultation service study that

coded every recommendation in the treatment and control groups together with its implementation using a standardised system [10]. Although there were slightly more recommendations per patient in some categories in the intervention group, implementation rates were comparable in the two groups. Similarity of care in the treatment and control groups might be the reason for the negative outcome in previous trials [1, 6].

Second, our entry criteria in the study may not have correctly identified the patients most likely to benefit from the intervention. Our study population was similar to other studies with respect to inclusion criteria. One-year mortality rate for patients in all the three groups of our study was ~20%, almost identical to mortality rates in other studies [2, 3, 5, 6]. In our analysis of subgroups that might have benefited more from the service, we found no effect of the intervention. It is thus unlikely that different inclusion criteria would have changed the results.

A third explanation is that the consultation teams were ineffective. They provided a more intensive intervention than many other consultation service studies and met the criteria generally accepted to characterise well-functioning teams. Processes of care were equivalent to those of other effective programmes [3, 14]. However, we failed to demonstrate that documented care recommendations or implementation was any different between groups, and this warrants further investigation. There is much debate about why dedicated inpatient units might be more effective, but it is possible that aspects of nursing management or interdisciplinary collaboration are important and cannot be influenced by a consultation service alone.

Finally, an intervention lasting 22–24 days on average might not be expected to have effects persisting for as long as a year. However, the data we do have for 3 months do not suggest any differences even at this time point.

Several limitations of our study should be noted. First, a high number of patients withdrew their consent, and this may have introduced bias. We were unable to explore this

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further because of data protection laws but performed a sensitivity analysis using dropout numbers, which suggested that patients who dropped out could not have changed the conclusions on the primary endpoints. However, there still remains a possibility of a false-negative result, due to by chance imbalance of the groups at baseline. Dropout was mainly due to the request for follow-up examination, where a research physician visited the patient and her relatives at home. Previous studies collected outcome data by accessing health documents/death certificates [3, 4, 6] or doing telephone interview [2, 5]. In our study, we aimed at obtaining broad and reliable outcome data by a personal interview and full examination, with the cost of a higher dropout rate.

Secondly, the setting of our study was in a medical system with high numbers of independent care providers paid by sickness funds, and with limited co-operation between hospitals, GPs and other care may have influenced outpatient care.

We conclude that a consultation model for providing specialist, multidiscipliary assessment and care for frail older hospitalised patients is ineffective in improving outcomes.

Key points

- Randomised clinical trial with 345 frail elderly patients plus 90 additional patients as an external comparison group.
- Patients randomly assigned to geriatric consultations and follow-up or usual care.
- After 12 months' follow-up, consultation teams did not improve rates of rehospitalisation or nursing home placement.
- No difference in survival, functional, emotional and cognitive status, social situation and quality of life after 12 months between groups.
- This is not due to carry-over effects of geriatric knowledge into the control group.

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Conflicts of interest

None of the authors had a conflict of interest. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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